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(54) Gas assist molding of one-piece catheters

Durch Gas unterstütztes Formen von einteiligen Kathetern

Moulage assisté par gaz de cathéters en une pièce

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(73) Proprietor: **Medex, Inc.**
Carlsbad, California 92008 (US)

(72) Inventors:
- **Goral, David**
  Brookfield,
  Connecticut 06804 (US)
- **Kafrawy, Adel**
  Kingston,
  Masssachusetts 02364 (US)
- **Polley, William F.**
  Duncanville,
  Texas 75137 (US)
- **Thomas, Joseph R.**
  Southlake,
  Texas 76092 (US)

(74) Representative: **Mercer, Christopher Paul**
Carpmaels & Ransford
43, Bloomsbury Square
London WC1A 2RA (GB)

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Description

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] This invention relates generally to a method and an apparatus for forming an intravascular device and more specifically for fabricating a catheter device.

Description of Related Art

[0002] Intravascular devices such as catheter assemblies are generally used for passing fluids between a device such as a syringe or a drip to or from body lumens such as veins or arteries, or other internal target sites. Such an assembly usually includes a hub, a catheter tube, and a needle. An eyelet ring is typically inserted into the catheter tube. The catheter tube, together with the eyelet ring, is then inserted into an opening in the nose of the hub and is secured to the hub by press fitting the eyelet ring within the nose of the hub. This hub and tube assembly is then mounted over a sharp needle which is in turn attached to a plastic hub. The sharp tip of the needle is used for piercing a body lumen so that access may be gained into the body lumen by the needle and subsequently the catheter. Once the catheter and the needle are located within the body lumen, the needle is removed and discarded while the catheter tube remains in the body lumen. A syringe or a tube of a drip is then attached to the hub so that fluids may be passed through the hub and the catheter between the drip or the syringe and the body lumen. The hub is typically made of materials that provide sufficient rigidity to securely attach drip lines thereto and the catheter tube is usually made of a material which is flexible and soft to minimize bodily injury.

[0003] Catheters comprising a separate hub and needle are known from US-A-5,380,301. This document describes a catheter which includes a mechanical connection between the strain relief thereof and the hub. The strain relief operates both to secure the catheter tube to the hub and to provide strain relief for the catheter tube. The strain relief connection is assisted in gripping the catheter tube by inteational overstressing of the catheter hub during manufacture thereof to expand the hub wall and generate residual hoop stresses therein which assist in securing the catheter tube within the hub.

[0004] US-A-5,641,184 discloses a tube made of plastic with a body in the wall of the tube which body can be pierced by a hypodermic needle. The body has sealing elements extending therefrom. The tube is molded around the body and sealing elements. A tool is provided which includes an upper and lower portion with the body being intially molded in the upper portion and then the portiosn are rotated 180 degrees and the tube is then molded around the body.

[0005] Hubs used in catheter assemblies are generally made by using injection molding. However, over-the-needle catheter tubes are usually made by an extrusion process and cut into short pieces instead of a single injection molded piece for two reasons. First, it is generally considered impractical to use a core pin of the same length as the tube in a conventional core pin injection molding process. This is because the core pin is often bent or broken in a high speed manufacturing environment resulting in frequent down time. Second, it is also generally thought by those skilled in the art that the gas assisted injection molding process cannot be used because the length of the tube in relation to the thickness of the thin wall exceeds the generally accepted aspect ratio of greater than 200. The aspect ratio is the length of the cylinder or tube divided by the wall thickness of that cylinder or tube.

[0006] WO 90/00960 discloses a process for producing thin walled tubes with connecting elements by injection moulding. The process produces cylindrical, thin walled tubes having a length of 10 to 150 mm and an outer diameter of maximum 2.5 mm and a wall thickness of 0.08 to 0.50 mm with a oonnecting means by injection moulding. A core of the mould holds the tub open within the mould and is centered by means of a movable sleeve.

[0007] The document - E. Haberstroh, et al: *"Prozeßsichere Verarbeitung von Flüssigsilikonkautschuk (LSR) zu technischen Formteilen"*, Kunststoffe 89 (1991) 1, Pages 68 to 72, Carl Hanser Verlag, München describes gas injection procedures for liquid silicon rubber. The document states that this allows the manufacture of complex elastomer construction components with functional cavities. These components can be used in medical technology as catheter, infusion tube and drainage items, as seals and as compound items of hard and soft material in two-component technology, formed, for example, by spraying stiff flanges directly onto conduits of elastomeric materials.

[0008] The document - K. Rahnhöfer: *"Gasinnendruckprozeß ist mehr als eine Alternative"*, Kumtstoffverarbeiter 41 (1996) 9, Page 24 to 27, Kunststoff Verlag, Isernhagen also describes gas injections for various uses, including sprayed on parts (adaptors and connectors), Bowden cables, and as insertion aids for heart catheters and similar products.

[0009] Although Plastic needles have been manufactured using infection molding with gas assist manufacturing as shown in US-A-5,620,639, a plastic needle is very different than a catheter. First, the geometry of a needle is quite different from that of an intravenous catheter. A needle requires the presence of a sharp point on the distal end of the needle to ease the penetration of the needle into the vascular system, whereas an over-the-needle catheter requires a bevel or taper at the distal end in order to provide a smooth entry of the catheter into the vascular system. The bevel

must fit precisely over the needle to allow for the smooth entry of the catheter into the vascular system with the least trauma to the patient. Second, a needle requires the use of a high modulus material for the efficient penetration of the vascular system in contrast to catheters that require flexible and soft materials to minimize bodily injury. Materials with tensile modulii above 10,000 megapascals (MPa), such as liquid crystal polymers and fiber-filled polyamides, are generally suitable for the production of plastic needles whereas materials with tensile modulii of less than 300 MPa are suitable for catheters. Additionally, over-the-needle catheters must have flow rates of the fluids that are to be provided to the patient to conform with ISO International Standard 10555-5, whereas there is no such standard for needles. It is therefore desirable to use a material capable of forming a lengthy, soft and flexible tube for an intravascular device that includes a bevel at the distal end of the tube and a luer lock at the proximal end of a hub.

SUMMARY OF THE INVENTION

[0010] According to the present invention there is provided an apparatus and a method for manufacturing an integral one-piece catheter having a tube and a hub by using a gas assisted injection molding process as defined in the appendent claims.

[0011] The method comprises feeding molten material into a mold having a mold cavity. In one embodiment, the molten material is injected near or into the hub portion of the cavity. In another embodiment, the molten material is injected into the catheter tube portion of the mold. While the polymer is introduced into the cavity, a fluid such as a gas is then injected through an inlet of the mold into the material in the cavity forming a channel throughout the center of the injected material. This may also cause a portion of the molten polymer to be displaced by the gas into a spillover exit.

[0012] Another embodiment of the invention involves forming a first portion of an intravascular device using a first material in a first mold. Thereafter the first portion of the intravascular device is inserted into a second mold to form a second portion using a second material. The second mold is formed on or around the first mold. A fluid such as a gas is then injected through an inlet of the mold into the cavity forming a channel throughout the center of the tube cavity. This may result in a portion of the molten polymer to be displaced by the gas into a spillover exit area.

[0013] In yet another embodiment of the invention, a first portion of the mold is injected with a first material, and a second portion of the cavity is injected with a second material at or around the same time that the first material is injected into the first portion of the cavity. A fluid such as a gas is injected through an inlet of the mold into the cavity. This causes a portion of the molten polymer to be displaced by the gas to conform to the mold with excess material displaced into the spillover exit area. In another embodiment of the invention, injected polymer is precisely measured to prevent spillover of excess molten polymer. In both of the previous cases, a hollow channel is formed throughout the center of the tube cavity.

[0014] Additional features, embodiments, and benefits will be evident in view of the figures and detailed description presented herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The features, aspects, and advantages of the invention will become more thoroughly apparent from the following detailed description, appended claims, and accompanying drawings in which:

Figure 1 shows the rheological properties (*i.e.*, viscosity versus shear rate) of polypropylene.

Figure 2 shows the rheological properties (*i.e.*, viscosity versus shear rate) of a thermoplastic elastomer sold under the trademark of C-FLEX™ blended with polypropylene at a weight percent ratio of 80/20.

Figure 3 shows the rheological properties (*i.e.*, viscosity versus shear rate) of a thermoplastic elastomer sold under the trademark of C-FLEX™ blended with polypropylene at a weight percent ratio of 85/15.

Figure 4 shows the rheological properties (*i.e.*, viscosity versus shear rate) of a thermoplastic elastomer sold under the trademark of C-FLEX™ blended with polypropylene at a weight percent ratio of 90/10.

Figure 5 shows the rheological properties (*i.e.*, viscosity versus shear rate) of a thermoplastic elastomer sold under the trademark of C-FLEX™.

Figure 6 shows the rheological properties (*i.e.*, viscosity versus shear rate) of OCRILON™ polyurethane.

Figure 7 shows a one-piece catheter device that is formed by practicing the invention.

Figure 8 shows a top view of a mold used to form an intravascular device in accordance with an embodiment of the invention.

Figure 9 shows the mold of Figure 8 wherein molten material is injected into the mold though the hub side of the cavity.

Figure 10 shows the mold of Figure 8 wherein a fluid such as a gas enters the mold in order to cause the polymer to move through the hub side of the cavity.

Figure 11 shows the mold of Figure 8 filled with molten material and with a hollow channel formed by the passage of gas through the cavity.

Figure 12 shows a cross-sectional view of the mold of Figure 8 wherein the first half and second half of the mold are separated.

Figure 13 shows a top view of a mold wherein a fluid is introduced through the tube of the catheter device in accordance with an embodiment of the invention.

Figure 14 shows molten material injected into two cavities for forming two catheters in accordance with an embodiment of the invention.

Figure 15 shows molten material moving through the cavity tube of the catheter with the force of gas passing through the tube in accordance with an embodiment of the invention.

Figure 16 shows that the molten material has filled the cavities of the mold and with a hollow channel formed by the passage of gas through the cavity in accordance with an embodiment of the invention.

Figure 17 shows the first half of the mold being separated from the second half of the mold in accordance with an embodiment of the invention.

Figure 18 shows a first portion of an intravascular device such as a hub that has a base or connector in accordance with an embodiment of the invention.

Figure 19 shows the same mold as Figure 17 except the molten polymer has been injected into a portion of the hub cavity and the polymer is beginning to solidify in accordance with an embodiment of the invention.

Figure 20 shows the hub cavity filled with polymer in accordance with an embodiment of the invention.

Figure 21 shows the first half of the mold separated from the second half of the mold in accordance with an embodiment of the invention.

Figure 22 shows the hub that was formed in Figures 18-20 is inserted into a second mold in accordance with an embodiment of the invention.

Figure 23 shows a mold wherein molten polymer has been fed into a portion of the tube cavity in accordance with an embodiment of the invention.

Figure 24 shows the progression of the molten polymer moving from the proximal portion of the tube to the distal portion of the tube in accordance with an embodiment of the invention.

Figure 25 shows the polymer continuing to move to the distal portion of the tube in accordance with an embodiment of the invention.

Figure 26 continues to show the gas being injected into the gas pin and the polymer has almost filled the tube cavity in accordance with an embodiment of the invention.

Figure 27 shows that the gas injection has been terminated at the gas pin and the tube cavity is filled with polymer in accordance with an embodiment of the invention.

Figure 28 shows a cross-section of the hollowed out portion of the tube formed for the intravascular device in accordance with an embodiment of the invention.

Figure 29 shows the first half of the mold separated from the second half of the mold in accordance with an embodiment of the invention.

Figure 30 shows an apparatus used to rotate the molds to different locations.

Figure 31 shows the hub and tube cavity of the one-piece catheter and a portion of an apparatus used in multi-component injection molding in accordance with an embodiment of the invention.

Figure 32 shows molten polymer fed into a portion of the hub cavity in accordance with an embodiment of the invention.

Figure 33 shows an insert moving to a position allowing the first cavity and the second cavity to be in communication with one another in accordance with an embodiment of the invention.

Figure 34 shows a mold wherein the hub has been formed by a polymer and a portion of the tube is formed in accordance with an embodiment of the invention.

Figure 35 shows polymer filling a portion of the tube cavity in accordance with an embodiment of the invention.

Figure 36 shows the hub and tube have been formed in accordance with an embodiment of the invention.

Figure 37 shows a plurality of cavities in a mold used to form a hub and a tube.

Figure 38 shows a mold with multiple cavities for forming intravascular devices.

DETAILED DESCRIPTION OF THE INVENTION

[0016] In the description that follows, the invention is described with reference to specific embodiments thereof. It will, however, be evident that various modifications and changes may be made thereto without departing from the scope of the invention as set forth in the claims. The specification and drawings are, accordingly, to be regarded in an illustrative rather than a restrictive sense.

[0017] One embodiment of the invention relates to forming a one-piece catheter using gas assist injection molding manufacturing of material described below. The catheter may be formed by using two separate cavities that form a first portion and a second portion. Additionally, a first polymer and a second polymer may be injected into each cavity. In another embodiment, a one-piece catheter may be formed from a single cavity using one polymer. In another embodiment of the invention, a connector such as a luer lock may be formed. The luer lock allows for the fastening of external delivery tubing to the hub of the intravenous device.

[0018] There are significant advantages to using gas assist injection molding manufacturing in order to form a one-piece catheter tube and hub compared to the conventional method of injection molding of the hub, extrusion of the tube, and assembling of both of these elements using an eyelet. The gas assist injection molding manufacture of a one-piece catheter typically costs less than that of the traditional method used to manufacture a catheter (*i.e.*, (a) injection molding of the hub, (b) extrusion of the catheter tube, and (c) the assembly of both using an eyelet). Moreover, the time used for forming a one-piece catheter is reduced due to the ease of using a single gas assist injection process. The one-piece catheter gas assist injection molding process is also less complicated than the conventional processes listed in (a) through (c) provided above. For example, assembly of two or more pieces is not required of the device formed from practicing the invention. Additionally, the bevel at the distal end of the tube does not have to be formed using subsequent thermal or laser operations because the mold incorporates the bevel shape directly into the mold itself.

[0019] Quality and productivity is also increased using the one-piece gas assist manufacturing process. For example, when a hub and a tube are separately formed, the hub may have a defect at the nose section of the hub that may not be noticed until after a hub is fitted to a tube. A large amount of hubs may have been formed before the defect is discovered thereby decreasing productivity. Similarly, in traditional manufacturing, tubing produced with dimensional errors results in numerous tubes that must be discarded. In comparison, a one-piece catheter eliminates this problem by forming the entire one-piece catheter simultaneously or at about the same time using a mold that incorporates the precise dimensions required by a particular catheter device.

[0020] In the discussion provided below, the materials and equipment used to practice the invention are provided

followed by the dimensions of the portions (*e.g.*, hub and tube) of the one-piece catheter that may be fabricated practicing the invention. Thereafter, numerous embodiments of the invention are presented.

Selection of Material for Hub

[0021] A variety of materials may be used to practice the invention. Material selection for the hub and the tube is based upon several factors such as rheological properties (*i.e.*, viscosity vs. shear rate), flexural modulus, the hardness of the material, and melt flow. As shown in **Figures 1-6**, the materials should be selected wherein the slope of the viscosity and shear rate is approximately the absolute value of 1.0 poise•seconds or greater. For example, **Figure 1** shows the rheological properties of polypropylene. **Figure 1** further provides a slope of -0.433. **Figure 2** shows the rheological properties of a thermoplastic elastomer sold under the trademark of C-FLEX™ blended with polypropylene. There is a 80/20 by weight ratio of C-FLEX™ to polypropylene. **Figure 2** further provides a slope of -3.16. **Figure 3** shows the rheological properties of a thermoplastic elastomer sold under the trademark of C-FLEX™ blended with polypropylene. There is approximately a 85/15 ratio by weight of C-FLEX™ to polypropylene. **Figure 3** further provides a slope of -0.82. **Figure 4** shows the rheological properties of a thermoplastic elastomer sold under the trademark of C-FLEX™ wherein the ratio by weight of C-FLEX™ to polypropylene is approximately 90/10. **Figure 4** further provides a slope of -2.49. **Figure 5** shows the rheological properties of a thermoplastic elastomer sold under the trademark of C-FLEX™. **Figure 5** further provides slopes of approximately -1.54 and -2.26. It is preferable to use C-FLEX™ (90A) or Santoprene® (rheological properties not shown in **Figure 5**). Melt flow that is highly shear sensitive is preferred as shown by a steep slope such as a slope of an absolute value of 1 or greater.

[0022] Figure 6 shows the rheological properties of a polyurethane available under the trademark of OCRILON™ polyurethane (a proprietary polyurethane of Johnson & Johnson Medical). The slope in **Figure 6** is -6.7.

[0023] Table 1 provides a summary of some of the slopes taken from the curves presented in **Figures 1-6.**

Table 1 Shear Sensitivity of Selected Polymers
Summary of Slope Data

Type	Polymer	Temperature (C)	Slope
Nylon	ULTRAMID B3™	250	-0.003
Polypropylene	polypropylene	210	-0.433
Polypropylene Blends	80/20 C-FLEX™/polypropylene	210	-3.16
	85/15 C-FLEX™/polypropylene	210	-0.82
	90/10 C-FLEX™/polypropylene	210	-2.49
	90/10 C-FLEX™/polypropylene	175	-7.8
Thermoplastic Elastomer	C-FLEX™ 90A (Clear)	210	-1.54
	C-FLEX™ 90A (White)	210	-2.26
ABS/Polyurethane Blend	PREVAIL™ 3050	230	-0.073
		220	-0.61
		210	-1.95
Elastomeric Polyamides	Polyetheramide (PEBAX™)	265	-5.56
		250	-5
Polyurethane	OCRILON™	210	-6.7

[0024] In addition to rheological properties, the flexural modulus of the material is considered in selecting a polymer. The flexural modulus of the catheter tubing that is fabricated should be approximately 50,000 psi (344 MPa) or higher when the catheter tubing is dry and less than 35,000 psi (241 MPa) when the catheter tubing is hydrated. A flexural modulus approximately in the range of 25,000 psi (172 MPa) and below is preferred for a catheter tubing that is hydrated and 85,000 psi (586 MPa) to 150,000 psi (1034 MPa) is preferred for a catheter tubing that is dry.

[0025] The hardness of the material is also considered in selecting a polymer. Materials exhibiting a hardness approximately in the range of 40 to 75 shore D is preferable.

[0026] Examples of the types of conventional materials that may be used in this molding process for the hub include:

- polyolefins such as polyethylene, polypropylene, TEFLON™ and fluoro-olefinic copolymers such as fluorinated ethylene propylene copolymer (FEP), and blends thereof;
- polyamides, polyetheramides, polyesteramides and blends thereof;
- polyesters;
- polyurethanes such as OCRILON™ resin, a proprietary optically clear radiopaque polyurethane from Johnson & Johnson Medical located in Arlington, Texas; TECOFLEX™ and TECOTHANE™ commercially available from Thermedics, Inc. located in Woburn, Massachusetts and blends of OCRILON™ resin, TECOFLEX™ and TECOTHANE™ ;
- polycarbonate-based polyurethanes such as CARBOTHANE™ commercially available from Thermedics, Inc., located in Woburn, Massachusetts and blends of OCRILON™, TECOFLEX™, and TECOTHANE™.
- Synthetic thermoplastic elastomers (*e.g.*, polyolefins filled with styrene-ethylene, butylene-styrene block copolymer and polydimethyl siloxane, etc.), an example of which is commercially available as C-FLEX™ from Consolidated Polymer Technologies, Inc. located in Largo, Florida; Santoprene® thermoplastic rubber (highly cross-linked rubber particles dispersed throughout a continuous thermoplastic matrix); commercially available from Advanced Elastomer Systems, Akron, OH; etc.
- Acrylonitrile-butadiene-styrene (ABS) polyurethane blends such as PREVAIL™ commercially available from Dow Chemical, Plastics Division, located in Midland, Michigan;
- Liquid crystal polymers (*e.g.* 2-napthalene carboxylic acid, 6-(acetyloxy) polymer with 4 (acetyloxy) benzoic acid, aromatic liquid crystal polyester, etc.) commercially available as VECTRA™ from Ticona, a division of Hoechst (Summit, New Jersey) and XYDAR™ from Amoco Polymers, Inc. located in Alpharetta, Georgia;
- Nylons (*e.g.*, commercially available as ULTRAMID B_3™ Nylon 6, and fiberglass reinforced nylon 6 commercially available from BASF Corporation located in Wyandotte, Michigan.
- Polyether nylons such as PEBAX 6333™ and PEBAX 2533™ commercially available from Elf Atochem North America, Inc. located in Philadelphia, Pennsylvania.

Although this list of compounds provides types of materials that generally may be used with the process described herein, it is to be appreciated that the invention is not limited to these compounds and other like or similar compounds or materials may also be used.

[0027] The preferred hub material to be used is C-FLEX™ and Santoprene® thermoplastic elastomer. With this type of material, the preferred barrel temperature range is 175-300°C and a preferred range of gas pressure used is 1,000-4,000 psi (6.9 MPa to 275 MPa). It will be appreciated that the barrel temperature for some of the materials listed above may reach above 300°C. For example, liquid crystal polymer may be heated to 350°C.

Selection of Material for Tube

[0028] The preferred materials that may be used for forming the tube include Teflon™ (*e.g.* fluorinated ethylene propylene copolymer), polyurethanes, rubber-filled polyolefins such as C-FLEX™ and Santoprene® thermoplastic elastomer. It will be appreciated that radiopacity inducing agents such as tungsten, barium sulfate, bismuth compounds and other suitable compounds may be combined with the tube materials. Radiopacity inducing agents permit a healthcare worker to locate a tube in a body in case the tube is broken and moves to a different location in the body. In the embodiment in which a one-piece catheter is produced from a single material, an optimum material is selected from any one of the materials listed above for the hub or for the tube except liquid crystal polymers.

Equipment

[0029] Molding machines that are most appropriate to practice the invention have high speed/low pressure injection capabilities such as the NIIGATA NN35MI™ machine commercially available from Daiichi Jitsugyo (America) located in Itasca, Illinois and equipped with a shut-off valve may be used with this and other machines. These machines are generally equipped with two sets of different sized injection cylinders that are symmetrically located and are diagonally opposed to each other and are on either side of the injector device. Injection molding machines use effective size (*e.g.* volume of the chamber as defined by length and the inner diameter of the cylindrical chamber) of the hydraulic injection cylinder as a pressure control with the flow control valve substantially open. A single cavity tool should use the high speed/low pressure injection molding machine with a low clamping tonnage such as in the range of 15 and 50 tons (149 kN and 498 kN). A screw diameter of 18 mm is preferred. The shot size used should be less than 4.0 ounces (113g). For multi-cavity tooling, a large tonnage (*e.g.*, up to 150 ton (1.5 MN)) machine may be required with shot sizes larger than 4 ounces (113g). Other conventional machines with shut-off valves are also suitable for this process.

[0030] In conjunction with injection molding machine, gas assist machines are used, such as the Bauer programmable NCU (Bauer Compressors located in Norfolk, Virginia). Preferred gas assist machines are those that are capable of

controlling multiple gas pressure phases.

Cavity Dimensions

[0031] The cavity size varies with the gauge of the catheter tube to be fabricated. For example, the outer diameter of the catheter tube made by the invention includes large 12 gauge such as 0.112 inches (2.84 mm) to small 26 gauge such as 0.0216 inches (0.55 mm). The inner diameter of the catheter tube ranges from 0.1 (2.54 mm) to 0.021 (0.53 mm) inches. The length of the tube ranges from 2-1/2 (63.5 mm) to 1/2 inch (12.7 mm). The hub has an inner diameter that ranges from 0.159 inches (4.04 mm) to 0.179 inches (4.55 mm) and an outer diameter that ranges from 0.31 inches (7.87 mm) to 0.32 inches (8.13 mm). Table 2 provides some examples of the specifications of different catheter tubes. However, it will be appreciated that other dimensions may also be used to practice the invention.

Table 2 Examples of Dimensions of Fabricated Tubes ((millimeters) (mm))

Outer Diameter Of Tube	Inner Diameter Of Tube	Length Of Tube	Wall Thickness Of Tube	Gauge
2.13	1.75	31	0.19	14
2.13	1.75	56	0.19	14
1.70	1.38	31	0.16	16
1.70	1.38	56	0.16	16
1.28	0.98	44	0.15	18
1.28	0.98	31	0.15	18
1.10	0.80	31	0.15	20
1.10	0.80	25	0.15	20
1.10	0.80	44	0.15	20
0.83	0.63	25	0.10	22
0.70	0.50	19	0.10	24

[0032] Figure 7 shows a one-piece catheter device 2 that is formed by practicing the invention. The one-piece catheter device has a tube portion 4 and a hub portion 6. It will be appreciated that tube portion 4 of the catheter device 2 is hollow therethrough. This hollow central portion is formed by gas assist injection molding. The hub portion is hollow in the central portion of the hub portion 6. At the distal end of hub portion 6 is nose 7. Nose 7 transitions into tube portion 4. Tube portion 4 ends with a tapered bevel 5 at the distal end of tube portion 4.

[0033] **Figures 8-12** show one embodiment of the invention wherein injection molding is used and a fluid such as inert gas (*e.g.*, nitrogen, air, helium, argon, etc.) is introduced through the hub portion of the mold to assist in forming the one-piece catheter hub component. Because the molten polymer enters the hub portion of the cavity, the hub is generally formed first followed by the formation of the tube. C-FLEX™ and Santoprene® thermoplastic elastomer, used under the operating conditions provided below, is generally capable of overcoming the known limitation of having an aspect ratio > 200 but yet still capable of providing a reliable product. **Figure 8** shows one-half of the mold used in manufacturing a one-piece catheter hub component. A second half (not shown) [first half (15) and second half (20)] is mated with the illustrated half to form mold 10. Pressure may be applied to the first half 15 against second half 20, to second half 20 against first half 15 or to both halves simultaneously to ensure that cavity 25 is tightly fitted or formed. Cavity 25 has a first portion that provides a tube and a second portion that provides a hub.

[0034] Mold 10 has an inlet 30 that allows molten polymer to enter mold 10. The molten polymer such as C-FLEX™ and/or Santoprene® thermoplastic elastomer is introduced to mold 10 at a pressure in the approximate range of 4,390 psi (30 MPa) to 40,000 psi (275 MPa). Additionally, the molten polymer is generally maintained at a temperature that ranges from 175°C to 220°C. It will be appreciated that other pressures and temperatures are possible depending upon the material used. The polymer then moves along runner 50 in the direction of hubs 16.

[0035] The two halves (15 and 20) meet at split line 22. At split line 22, inlet for fluid flow is not open for fluids such as nitrogen gas, air, helium, argon, etc. to enter mold 10. **Figure 8** further shows the feed material such as a polymer spreading from runner 50 to hub 16 for both devices.

[0036] **Figure 9** shows the same mold as **Figure 8** wherein a layer of the polymer forms on the cavity surface and begins to solidify. The solidified polymer covers a larger surface of the cavity compared to the solidified polymer shown

in mold 10 of **Figure 8**. The quantity of polymer introduced into cavity 25 is controlled to a small quantity to allow the fluid to advance the polymer further into the cavity surface of mold 10.

[0037] **Figure 10** shows a fluid such as gas (*e.g.* nitrogen gas, air, helium, argon, etc.) entering inlet 70 for mold 10. The gas is introduced from a low pressure of 500 psi (3.5 MPa) to as high as 9,000 psi (62 MPa) when gas is introduced during the injection molding process. As the gas passes through tube 75, pressure builds at the proximal end of hub 16 behind the polymer that was injected. This pressure causes the polymer to move in the distal direction of tube cavity 18. It will be appreciated that although gas is shown to be introduced after the polymer is fed into the cavity, the gas may be introduced simultaneously or about the same time as the molten polymer is fed into the cavity.

[0038] **Figure 11** shows mold 10 having hub 16 and tube 18 filled with polymer but with a hollow channel formed in the tube by the gas. The process of filling cavity 25 generally takes 0.5 to 5 seconds. Excess polymer exits an exit channel into a spillover area 13 of the mold. Alternatively, the precise amount of material is used and no polymer is considered excess. This is accomplished by measuring the amount of necessary polymer through applying a short-shot of material into the mold. The amount of polymer used is adjusted until the amount necessary to prevent spillover is determined by adjusting the amount of polymer introduced into cavity 25.

[0039] After the polymer has begun to solidify. **Figure 12** shows mold 10 wherein first half 15 is separated from second half 20. It will be appreciated that first and second halves (15 and 20) may be mated longitudinally or vertically. The single integral piece may then be removed or ejected by a mechanism in the mold (not shown). The process cycle represented by **Figures 8-12** may then be repeated. It will be appreciated that although **Figures 8-12** show two devices being manufactured simultaneously, other devices such as a single device or more than two devices, i.e., multiple devices can be manufactured simultaneously or at approximately the same time.

[0040] Preferably, a portion of the mold forms the beveled end of a tube. In this embodiment of the invention, a polymer is injected into the hub portion of each of the hub cavities. The polymer then fills the tube portion and the bevel of each of the tube cavities.

[0041] **Figures 13-17** show another embodiment on the invention wherein gas is introduced through the tube of the one-piece catheter and hub of mold 110. **Figure 13** shows a top view of mold 110 used to form a one-piece catheter and hub. **Figure 13** further shows a cavity portion for the hub 116 and the tube 118 for two devices. Material such as a polymer is heated until the temperature reaches the melt temperature of the polymer. The molten polymer then enters the tube side of the cavity at inlet 130 of mold 110. **Figure 13** further shows a gas pin 140 in communication with runner 150. Runner 150 communicates with the distal end of tube 118. **Figure 13** also shows spillover areas beyond hub 116 for the overflow of excess polymer.

[0042] **Figure 14** shows the device of **Figure 13** with molten material entering inlet 140. While the molten material begins to spread within cavity 125 for both devices. **Figure 14** further shows the molten polymer beginning to move in a proximal direction of tubes 118.

[0043] **Figure 15** shows that the polymer has continued to advance along tubes 118. Before the polymer fills cavity 125, the amount of polymer entering the cavity 125 is consumed. At this point, a fluid such as nitrogen gas, air, helium, argon, etc. enters inlet 170 and moves toward the general direction of runner 150 until the gas contacts the molten material. Upon contacting the molten material, the pressure begins to build behind the molten material and the gas pushes the molten material along the interior of cavity 125. The gas pressure is one of the contributing factors that causes the polymer to move through the remainder of the tube and hub cavity creating an interior channel throughout the cavity.

[0044] **Figure 16** shows cavity 125 is filled with the polymer material but with a hollow channel formed in the tube by the gas. After a certain time period such as 3-20 seconds, the two halves of the mold are opened and the part is ejected. **Figure 17** shows first half 115 and second half 120 being separated thereby allowing the one-piece catheter tube and hub devices to be separated from mold 110. The process represented by **Figures 13-17** may then be repeated.

[0045] **Figures 18-29** show another embodiment of the invention wherein at least two portions of the one-piece catheter component comprise at least two different materials. A first portion of the intravascular device is made using one material. For example, mold 210 has a cavity for a hub in which the hub portion may be formed first. Mold 210 is then moved or cycled around by a rotating platen in the molding machine (not shown). A second material (or, alternatively, the same material) may be injected into a second cavity to form a second portion of the intravascular device such as a tube.

[0046] **Figure 18** shows a first portion of an intravascular device such as a hub 216 that has a base or connector 235. Connector 235 may be either a male or female luer lock. Nose 228 is formed at the end that opposes connector 235. The dimensions of the luer lock should conform to ISO International Standards 594/1 and 594/2. Nose 228 is subsequently coupled to a tube portion of the intravascular device. **Figure 18** further shows the location 232 of where the polymer may be fed into the hub cavity. It will be appreciated, however, that the inlet to the cavity for the hub for injecting molten polymer may be located anywhere along the hub cavity. For example, molten polymer may be fed in at location 225. **Figure 19** shows the same first mold 210 as in **Figure 18** except the molten polymer has been injected into a portion of hub cavity 216 and the polymer is beginning to solidify.

[0047] **Figure 20** shows first mold 210 wherein the molten polymer has filled hub cavity 216 leaving a hollow central

portion in the hub. This process generally takes 1-3 seconds. Although gas assist injection molding is not typically used with a hub cavity, this process could be used in forming nose 228.

[0048] **Figure 21** shows in one embodiment that after the hub has been formed, first half 202 is separated from second half 204. The hub that is formed from first mold 210 is then ejected from second half 204 using traditional methods. It will be appreciated, however, that the hub may preferably remain in mold 210 and mold 210 is cycled or rotated around as shown in **Figure 30** and described in the accompanying text to second mold 218 wherein the hub is inserted into second mold 218. **Figure 22** shows the hub that was formed in the process disclosed in **Figures 18-21** is thereafter inserted into a second mold 218. Second mold 218 has a tube cavity 255 for forming a tube at the distal end of the hub. **Figure 22** further shows first half 290 and second half 280 of second mold 218. First half 290 and second half 280 are mated together to ensure that the molten polymer stays within the cavity that is present within second mold 218. At the proximal portion of the hub, gas pin 250 is inserted thereto. Gas pin 250 is located within the inner diameter of hub. A fluid such as a gas (e.g., nitrogen gas, air, helium, argon, etc.) is injected at the proximal end of gas pin 250 and exits outlet 242 of gas pin 250. The molten polymer may be fed into a variety of locations for tube cavity 255. Inlet 220 shows one location that may be used for injecting molten polymer into tube cavity 255.

[0049] **Figure 23** shows second mold 218 wherein molten polymer has been fed into a portion of tube cavity 255. It should be noted that the type of polymer that may be used for the tube of the catheter may be different from the polymer that is fed into the hub or they may be the same polymer as explained above. Materials used to form the tube are described above. **Figure 24** shows the progression of the molten polymer moving from the proximal portion of the tube to the distal portion of the tube.

[0050] **Figures 25-27** shows the polymer continuing to move to the distal portion of the tube cavity. Fluid such as gas is introduced at the proximal portion of gas pin 250 as shown in **Figures 25** and **26.** The pressure of the gas ranges from 50U psi (3.5 MPa) to 9,000 psi (62 MPa) and the gas is nitrogen gas, air, helium, argon, etc. The introduction of gas pushes the polymer to the distal portion of the tube leaving a polymer skin or tube wall next or adjacent to the mold surface and forming an internal lumen therein. As noted above, pressurized gas presses against the molten polymer causing the molten polymer to advance into regions of the cavity until the cavity is coated with molten polymer as shown in **Figure 27.** A hollow channel is also formed inside of the tube cavity. It will be appreciated however, that the pressure of the gas may vary depending upon the material chosen. Other operating conditions may also vary depending upon the materials used to typically form the one-piece catheter. It generally takes up to 60 seconds (typically, it takes less than 15 seconds) from the time molten polymer is introduced until the first cavity is filled. **Figure 27** shows that the gas introduction has been terminated at gas pin 250 and the tube cavity 255 is filled with polymer with a hollow center therethrough.

[0051] **Figure 28** further shows a cross-section of the tube being formed. It will be appreciated that the injection of the gas at gas pin 250 causes the tube to form a hollow central portion 256 of the tube as a result of gas assist injection molding manufacturing.

[0052] **Figure 29** shows first half 290 of mold 218 separated from second half 280 of second mold 218. The tube is formed and is partially separated from first half 280. The process represented by **Figures 18-29** may then be repeated.

[0053] **Figure 30** illustrates a manufacturing apparatus 400 that may be used to move a first mold that is used to form a hub or a tube to a second mold to form the other portion of the one-piece catheter. In one embodiment, a rotating mechanism (not shown) is built into the mold itself.

[0054] There are two molds for forming a first and a second portion (A, B) of the one-piece catheter. The manufacturing operation begins by forming a first portion (A) in a first mold. The first mold is comprised of two sections (410, 412) that are mated together. After the first portion such as a hub has been formed, the first mold is disengaged from position Y1 and moved or rotated to position Y2. The second mold comprised of two sections (420, 422) that are mated together is then secured to the first mold using conventional techniques to allow the formation of a second portion using the second mold. It will be appreciated that instead of the second mold being secured to a first mold after the first portion is formed, the first portion may be released using conventional techniques and a robot (not shown) may pick up the first portion (A) and place it into the second mold. Thereafter, the second portion (B) may be formed using the molding process described herein. Other apparatus used for moving a first portion (A) after formation include devices that have a turntable for rotating the mold from one position to another. The process represented by **Figures 18-30** may then be repeated.

[0055] **Figures 31-36** show another embodiment of the invention. In this embodiment, the hub and the tube mold cavities are initially physically separated from one another by an insert located between the distal end of the hub and the proximal end of the tube.

[0056] **Figure 31** shows a portion of an apparatus for multi-component injection molding and the cavities used to form the hub and the tube. Containers 214 and 215 are hoppers used to hold solid polymer particles or granules. The first polymer is melted and enters first barrel 216 of a double barreled injection molding machine and exits from nozzle 217. The molten first polymer enters hub cavity 270 through a sprue(s) and runner(s) and into gate 244. Insert 219 at the distal end of hub cavity 270 may move from a first position (X_1) to a second position (X_2). In its first position, insert 219 blocks off hub cavity 270 from tube cavity 255. Gas pin 250 is inserted into the central portion of hub cavity 270 similar

to that described above. **Figure 31** shows that a first polymer is injected into hub cavity 270 through gate 244 and molten polymer moves in two directions such as in the proximal direction of connector 235 and the distal direction of the hub nose. **Figure 32** shows the molten polymer has filled hub cavity 270. It will be appreciated that the central portion of the hub is hollow and only the outer structure of the hub is filled.

[0057] **Figure 33** shows insert 219 has moved to a second position X_2 from its prior position of X_1. This allows hub cavity 270 and tube cavity 255 to be in communication with one another and are no longer physically separated. At this point, the hub is formed and injection of a second polymer will combine at the interface with the first polymer. **Figure 34** shows that the second polymer has been fed into tube cavity 255 via hopper 215, barrel 221, and nozzle 223. The second polymer begins to move in the distal direction of tube cavity 255 through gate 248. In **Figure 35**, a fluid such as a gas (e.g. air, nitrogen gas, helium, argon, etc.) is introduced at inlet 250. Gas exits gas pin at 242 wherein the gas pin is inserted through hub cavity 270 and ends at the distal end of the nose portion 240 of hub cavity 270. Gas pushes the central portion of the molten polymer to the distal portion of tube cavity 255 forming a tube.

[0058] **Figure 36** shows the tube cavity filled with polymer. However, it will be appreciated that the gas has cored out a longitudinal hollow portion through the tube that is formed. The hollow portion extends from the proximal end to the distal end of the tube.

[0059] The hub and tube are then ejected from the mold as a single piece using conventional methods. It will be appreciated that tube cavity 255 could be filled before hub cavity 270 but it is preferred that the hub cavity is filled prior to filling tube cavity 255. Alternatively, hub cavity 270 and tube cavity 255 may be filled with different polymers or the same polymer either simultaneously or at about the same time. The process represented by **Figures 31-36** may then be repeated.

[0060] **Figure 37** shows another mold wherein a plurality of cavities may be used to form an integral hub and a tube. Gas pin 300 is inserted into the hub portion 310 of the device. In this embodiment of the invention, a polymer is injected into the hub portion of the cavity. During or after the hub has been formed, the tube portion 320 of the intravascular device is formed. Either a single polymer may be used to form the hub and the tube or two polymers may be used separately to form the hub and the tube as a single piece.

[0061] **Figure 38** shows another mold that may be used to practice the invention. Runner 50 communicates with a plurality of tubes 16 and hubs 18. The polymer is heated in a molding machine (not shown) until the polymer attains a molten state. The polymer is introduced at 24 into the mold and generally moves in the direction of all the cavities simultaneously or about the same speed. Gas pin 20 is used to introduce a fluid such as a gas into the cavity of the mold. This mold may be used with a single polymer or two polymers.

[0062] In the preceding detailed description, the invention is described with reference to specific embodiments thereof. It will, however, be evident that various modifications and changes may be made thereto without departing from the scope of the invention as set forth in the claims. The specification and drawings are, accordingly, to be regarded in an illustrative rather than a restrictive sense.

Claims

1. A method for manufacturing an integral, one-piece catheter (2) having a tube (4) and hub (6), comprising:

   feeding a molten polymer into a mold (10) having a mold cavity (25) with a tube portion (18) and a hub portion (16) extending from the tube portion (18); and
   injecting a fluid under pressure into a gate of the cavity (25) so that said fluid under pressure pushes said molten polymer through said mold cavity, thereby forming said hub (6) and said tube (4) having an orifice therethrough.

2. The method of claim 1, wherein, after feeding the first molten polymer into the mold (10), a second molten polymer is fed into the mold whereby either the hub (6) or the tube (4) of the catheter (2) is formed from the first polymer and the other portion of the catheter is formed from the second polymer.

3. The method of claim 1, further comprising:

   feeding a molten polymer into said mold cavity (125) along a runner (150) under pressure from a molding machine, a solidified layer of the polymer forming on the mold surface;
   introducing said fluid into the cavity to push molten polymer along the orifice created within the region of the cavity to form the orifice and to continue the passage of polymer along the remaining length of the cavity, completing the formation of the solidified layer of polymer on the mold surface.

4. The method of claim 1 or claim 3, wherein:

said molten polymer is injected into the mold (10) through an inlet to the hub portion of the cavity (25); and said fluid is introduced through the hub portion of the cavity (25), thereby forming said tube.

5. A method for manufacturing an integral, one-piece catheter (2) having a tube (4) and hub (6), comprising:

providing a first mold (210) having a cavity (216) for forming said hub (6) and a second mold (218) having a cavity (255) for forming said tube (4) attached to said hub (6);
injecting a first molten polymer into the cavity (216) of said first mold (210);
molding said hub (6) in said cavity (216) of said first mold (210);
removing said hub (6) from said cavity (216) of said first mold (210);
inserting said hub (6) into said second mold (218);
injecting a second molten polymer into said cavity (255) of said second mold (218);
injecting a fluid through an inlet (220) of said second mold (218) so that said fluid under pressure pushes said molten polymer through said mold cavity (220), thereby forming said tube (4) having an orifice therethrough.

6. The method of any one of claim 1 to 5, wherein the fluid is nitrogen, air, helium or argon.

7. The method of any one of claims 1 to 6, wherein the hub portion (216) has formed thereon a male lock or a female lock (235).

8. The method of any one of claims 1 to 7, wherein the flow rate of the polymer is sufficient so as to fill the cavity in 0.5 to 5 seconds.

9. The method of any one of claims 1 to 8, wherein:

the feeding of polymer continues until the cavity (25, 125) is filled; and
fluid is injected into the mold (10).

10. The method of any one of claims 1 to 9, wherein the outer diameter of the tube (4) increases along its length toward the hub and the increase in the diameter is substantially constant to provide a substantially straight taper.

11. The method of any one of claims 1 to 10, further comprising purging the fluid through an exit channel.

12. The method of any one of claims 1 to 11, wherein a radiopaque inducing agent is combined with the polymer.

13. The method of claim 12, wherein the radiopaque inducing agent is tungsten, barium sulphate or a bismuth compound.

14. The method of any one of claims 1 to 13, wherein a nose is formed between the hub and the tube.

15. The method of any one of claims 1 to 14, wherein the temperature of the molten material is approximately in the range of 175°C to 300°C, preferably 175°C to 220°C.

16. The method of any one of claims 1 to 15 wherein the pressure within the or each cavity of the mold is approximately in the range of 6.9 MPa to 275 Mpa (1,000 psi to 40,000 psi).

17. The method of any one of claims 1 to 16, wherein the second cavity is beveled at a distal end of the tube.

18. The method of any one of claims 1 to 17, wherein the polymer or the first polymer is a polyolefin filled with an elastomeric polymer, a polyesteramide, a polyurethane, a polyetheramide, a polycarbonate, a polyester, a polyamide, an acrylonitrile-butadiene-styrene, a fluorinated ethylene propylene copolymer or a liquid crystal polymer.

19. The method of any one of claims 1 to 18, wherein the polymer of the first polymer was selected based upon the slope of viscosity versus shear rate, wherein the negative slope is greater than an absolute value of 1.0.

20. The method of claim 5 or any claim dependent thereon, wherein the second polymer is a polyurethane, a polyfluoropolyolefin or an elastomeric component blended in polypropylene.

21. A mold for forming an integral, one-piece catheter (2) having a tube (4) and a hub (6) comprising:

a mold cavity with:

a tube portion (255), the distal end of which is beveled;
a hub portion (270) extending from the tube portion; and
a connector portion at the proximal end of the hub portion;

an aperture in the mold cavity for receiving a first molten polymer for injection into the hub portion and a second molten polymer for injection into the tube portion; and
a gate in the mold cavity through which a fluid under pressure is injectable into the mold cavity.

22. The mold of claim 21, wherein the connector portion is a male lock or a female lock.

23. The mold of claim 21 wherein the aspect ratio is greater than 200.

24. The mold of claim 21 wherein the connector portion is substantially cylindrical in shape.

25. The mold of claim 21, wherein the orifice is located in at least one of the hub portion and tube portion of the cavity.

26. The mold of claim 21, wherein a hub portion which is formed is from the hub portion of the mold cavity is rotated by a rotator coupled in the mold from a first position to a second position; and the hub portion is secured to a second mold.

Patentansprüche

1. Verfahren zur Herstellung eines integralen einteiligen Katheters (2) mit einem Rohr und einem Verbindungsstück (6), umfassend:

Zuführen eines geschmolzenen Polymers in eine Form (10) mit einer Formhöhlung (25) mit einem Rohrabschnitt (18) und einem Verbindungsabschnitt (16), der sich vom Rohrabschnitt (18) erstreckt; und
Injizieren eines Fluids unter Druck in einen Einlauf der Höhlung (25), so daß das unter Druck stehende Fluid das geschmolzene Polymer durch die Formhöhlung drückt, wodurch das Verbindungsstück (6) und das Rohr (4) mit einer Öffnung durch diese gebildet werden.

2. Verfahren nach Anspruch 1, wobei nach dem Zuführen des ersten geschmolzenen Polymers in die Form (10) ein zweites geschmolzenes Polymer in die Form zugeführt wird, wobei entweder das Verbindungsstück (6) oder das Rohr (4) des Katheters (2) aus dem ersten Polymer gebildet wird und der andere Teil des Katheters aus dem zweiten Polymer gebildet wird.

3. Verfahren nach Anspruch 1, des weiteren umfassend:

Zuführen eines geschmolzenen Polymers in die Formhöhlung (125) entlang eines Abstechkanals (150) unter Druck von einer Formmaschine, wobei sich eine verfestigte Schicht des Polymers auf der Formoberfläche bildet;
Einführen des Fluids in die Höhlung, um geschmolzenes Polymer längs der im Bereich der Höhlung erzeugten Öffnung zu pressen, um die Öffnung zu formen und um den Durchgang des Polymers über die verbleibende Länge der Höhlung fortzusetzen, wodurch die Ausbildung der verfestigten Schicht aus Polymer auf der Formoberfläche vervollständigt wird.

4. Verfahren nach Anspruch 1 oder 3, wobei:

das geschmolzene Polymer durch einen Einlauf zum Verbindungsabschnitt der Höhlung (25) in die Form (10) injiziert wird; und
das Fluid durch den Verbindungsabschnitt der Höhlung (25) eingeführt wird, wodurch das Rohr gebildet wird.

5. Verfahren zur Herstellung eine integralen, einteiligen Katheters (2) mit einem Rohr (4) und einem Verbindungsstück (6), umfassend:

Bereitstellen einer ersten Form (210) mit einer Höhlung (216) zur Ausbildung des Verbindungsstücks (6) und einer zweiten Form (218) mit einer Höhlung (255) zur Ausbildung des am Verbindungsstück (6) befestigten

Rohrs (4);
Injizieren eines ersten geschmolzenen Polymers in die Höhlung (216) der ersten Form (210);
Formen des Verbindungsstücks (6) in der Höhlung (216) der ersten Form (210);
Entfernen des Verbindungsstücks (6) aus der Höhlung (216) der ersten Form (210);
Einfügen des Verbindungsstücks (6) in die zweite Form (218);
Injizieren eines zweiten geschmolzenen Polymers in die Höhlung (255) der zweiten Form (218);
Injizieren eines Fluids durch einen Einlauf (220) der zweiten Form (218), so daß das unter Druck stehende Fluid das geschmolzene Polymer durch die Formhöhlung (220) drückt, wodurch das Rohr (4) mit einer Öffnung durch dieses gebildet wird.

6. Verfahren nach einem der Ansprüche 1 bis 5, wobei das Fluid Stickstoff, Luft, Helium oder Argon ist.

7. Verfahren nach einem der Ansprüche 1 bis 6, wobei der Verbindungsabschnitt (216) einen daran ausgebildeten Verschlußvorrichtungsstecker oder Verschlußvorrichtungsbuchse (235) aufweist.

8. Verfahren nach einem der Ansprüche 1 bis 7, wobei die Strömungsrate des Polymers ausreichend ist, um die Höhlung in 0,5 bis 5 Sekunden zu füllen.

9. Verfahren nach einem der Ansprüche 1 bis 8, wobei:

das Zuführen von Polymer andauert, bis die Höhlung (25, 125) gefüllt ist; und Fluid in die Form (10) injiziert wird.

10. Verfahren nach einem der Ansprüche 1 bis 9, wobei der äußere Durchmesser des Rohrs (4) längs seiner Länge zum Verbindungsstück zunimmt und die Zunahme des Durchmessers im wesentlichen konstant ist, so daß ein im wesentlichen gerader Konus erhalten wird.

11. Verfahren nach einem der Ansprüche 1 bis 10, das des weiteren ein Spülen des Fluids durch einen Ausgangskanal umfaßt.

12. Verfahren nach einem der Ansprüche 1 bis 11, wobei ein Röntgendichtigkeitinduzierendes Agens mit dem Polymer kombiniert wird.

13. Verfahren nach Anspruch 12, wobei das Röntgendichtigkeit-induzierende Agens Wolfram, Bariumsulfat oder eine Wismutverbindung ist.

14. Verfahren nach einem der Ansprüche 1 bis 13, wobei zwischen dem Verbindungsstück und dem Rohr eine Nase gebildet wird.

15. Verfahren nach einem der Ansprüche 1 bis 14, wobei die Temperatur des geschmolzenen Materials ungefähr im Bereich von 175°C bis 300°C und vorzugsweise 175°C bis 220°C liegt.

16. Verfahren nach einem der Ansprüche 1 bis 15, wobei der Druck in der oder in allen Höhlungen der Form ungefähr im Bereich von 6,9MPa bis 275 MPa (1.000 psi bis 40.000 psi) liegt.

17. Verfahren nach einem der Ansprüche 1 bis 16, wobei die zweite Höhlung an einem distalen Ende des Rohrs abgeschrägt ist.

18. Verfahren nach einem der Ansprüche 1 bis 17, wobei das Polymer oder das erste Polymer ein mit einem elastomerischen Polymer, einem Polyestheramid, einem Polyurethan, einem Polyetheramid, einem Polykarbonat, einem Polyester, einem Polyamid, einem Akylnitril-Butadien-Styren, einem fluorinierten Ethylenpropylenkopolymer oder einem Flüssigkristallpolymer gefülltes Polyolefin ist.

19. Verfahren nach einem der Ansprüche 1 bis 18, wobei das Polymer des ersten Polymers basierend auf der Steigung der Viskosität in Abhängigkeit von der Scherrate gewählt wurde, wobei die negative Steigung größer ist als ein Absolutwert von 1,0.

20. Verfahren nach Anspruch 5 oder nach einem beliebigen davon abhängigen Anspruch, wobei das zweite Polymer ein Polyurethan, ein Polyfluorpolyolefin oder eine Elastomerkomponente ist, die mit Polypropylen gemischt ist.

21. Form zum Formen eines integralen einteiligen Katheters (2) mit einem Rohr (4) und einem Verbindungsstück (6), umfassend:

eine Formhöhlung mit:

einem Rohrabschnitt (255), wobei das distale Ende desselben abgeschrägt ist;
einem Verbindungsabschnitt (270), der sich vom Rohrabschnitt erstreckt; und
einem Steckeranschluß am proximalen Ende des Verbindungsabschnitts; und

eine Öffnung in der Formhöhlung zur Aufnahme eines ersten geschmolzenen Polymers zur Injektion in den Verbindungsabschnitt und eines zweiten geschmolzenen Polymers zur Injektion in den Rohrabschnitt; und einen Einlauf in der Formhöhlung, durch den ein unter Druck stehendes Fluid in die Formhöhlung injizierbar ist.

22. Form nach Anspruch 21, wobei der Steckerabschnitt ein Verschlußvorrichtungsstecker oder eine Verschlußvorrichtungsbuchse ist.

23. Form nach Anspruch 21, wobei das Längenverhältnis größer als 200 ist.

24. Form nach Anspruch 21, wobei der Steckerabschnitt eine im wesentlichen zylindrische Form aufweist.

25. Form nach Anspruch 21, wobei sich die Öffnung zumindest im Verbindungsabschnitt oder im Rohrabschnitt der Höhlung befindet.

26. Form nach Anspruch 21, wobei ein Verbindungsabschnitt, der aus dem Verbindungsabschnitt der Formhöhlung ausgebildet ist, mit einem mit der Form gekoppelten Rotator aus einer ersten Position in eine zweite Position gedreht wird, und der Verbindungsabschnitt an einer zweiten Form befestigt ist.

Revendications

1. Méthode de fabrication d'un cathéter intégral en une pièce (2) ayant un tube (4) et un raccord (6), comprenant les étapes consistant à :

introduire un polymère fondu dans un moule (10) ayant une cavité de moule (25) avec une partie de tube (18) et une partie de raccord (16) s'étendant à partir de la partie de tube (18) ; et
injecter un fluide sous pression dans un seuil de la cavité (25) de telle façon que ledit fluide sous pression pousse ledit polymère fondu à travers ladite cavité de moule, formant ainsi ledit raccord (6) et ledit tube (4) ayant un orifice le traversant.

2. Méthode selon la revendication 1, dans laquelle, après introduction du premier polymère fondu dans le moule (10), un second polymère fondu est introduit dans le moule, de telle manière que le raccord (6) ou le tube (4) du cathéter (2) est formé dans le premier polymère et l'autre partie du cathéter est formée dans le second polymère.

3. Méthode selon la revendication 1, comprenant en outre les étapes consistant à :

introduire un polymère fondu dans ladite cavité de moule (125) le long d'un canal (150) sous pression à partir d'une machine de moulage, une couche solidifiée du polymère se formant sur la surface du moule ;
introduire ledit fluide dans la cavité pour pousser le polymère fondu le long de l'orifice créé à l'intérieur de la région de la cavité pour former l'orifice et continuer le passage du polymère sur la longueur restante de la cavité, ce qui achève la formation de la couche solidifiée de polymère sur la surface du moule.

4. Méthode selon la revendication 1 ou la revendication 3, dans laquelle:

ledit polymère fondu est injecté dans le moule (10) à travers une entrée menant à la partie de raccord de la cavité (25) ; et
ledit fluide est introduit à travers la partie de raccord de la cavité (25), formant ainsi ledit tube.

5. Méthode de fabrication d'un cathéter intégral en une pièce (2) ayant un tube (4) et un raccord (6), comprenant les

étapes consistant à :

préparer un premier moule (210) ayant une cavité (216) pour former ledit raccord (6) et un second moule (218) ayant une cavité (255) pour former ledit tube (4) attaché au dit raccord (6) ;
injecter un premier polymère fondu dans la cavité (216) dudit premier moule (210) ;
mouler ledit raccord (6) dans ladite cavité (216) dudit premier moule (210) ;
retirer ledit raccord (6) de ladite cavité (216) dudit premier moule (210) ;
insérer ledit raccord (6) dans ledit second moule (218) ;
injecter un second polymère fondu dans ladite cavité (255) dudit second moule (218) ;
injecter un fluide à travers une entrée (220) dudit second moule (218) de telle façon que ledit fluide sous pression pousse ledit polymère fondu à travers ladite cavité de moule (220), formant ainsi ledit tube (4) ayant un orifice le traversant.

6. Méthode selon l'une quelconque des revendications 1 à 5, dans laquelle le fluide est de l'azote, de l'air, de l'hélium ou de l'argon.

7. Méthode selon l'une quelconque des revendications 1 à 6, dans laquelle la partie de raccord (216) comporte un verrou mâle ou un verrou femelle (235) formé sur celle-ci.

8. Méthode selon l'une quelconque des revendications 1 à 7, dans laquelle le débit du polymère est suffisant pour remplir la cavité en 0,5 à 5 secondes.

9. Méthode selon l'une quelconque des revendications 1 à 8, dans laquelle:

l'introduction de polymère se poursuit jusqu'à ce que la cavité (25, 125) soit remplie ; et
le fluide est injecté dans le moule (10).

10. Méthode selon l'une quelconque des revendications 1 à 9, dans laquelle le diamètre extérieur du tube (4) augmente sur sa longueur vers le raccord et l'augmentation de diamètre est sensiblement constante pour produire une conicité sensiblement droite.

11. Méthode selon l'une quelconque des revendications 1 à 10, comprenant en outre la purge du fluide à travers un canal de sortie.

12. Méthode de l'une quelconque des revendications 1 à11, dans laquelle un agent inducteur radio-opaque est combiné au polymère.

13. Méthode selon la revendication 12, dans lequel l'agent inducteur radio-opaque est du tungstène, du sulfate de baryum ou un composé de bismuth.

14. Méthode selon l'une quelconque des revendications 1 à 13, dans laquelle un nez et formé entre le raccord et le tube.

15. Méthode selon l'une quelconque des revendications 1 à 14, dans laquelle la température de la matière fondue se situe approximativement dans la plage de 175 °C à 300 °C, de préférence de 175 °C à 220 °C.

16. Méthode selon l'une quelconque des revendications 1 à 15, dans laquelle la pression à l'intérieur de la cavité ou de chaque cavité du moule se situe approximativement dans la plage de 6,9 MPa à 275 MPa (1000 psi à 40 000 psi).

17. Méthode selon l'une quelconque des revendications 1 à 16, dans lequel la seconde cavité est biseautée à une extrémité distale du tube.

18. Méthode selon l'une quelconque des revendications 1 à 17, dans laquelle le polymère ou le premier polymère est une polyoléfine chargée d'un polymère élastomère, un polyesteramide, un polyuréthane, un polyétheramide, un polycarbonate, un polyester, un polyamide, un acrylonitrile-butadiène-styrène, un copolymère d'éthylène propylène fluoré ou un polymère cristal liquide.

19. Méthode selon l'une quelconque des revendications 1 à 18, dans laquelle le polymère du premier polymère a été choisi sur base de la pente de viscosité en fonction du taux de cisaillement, dans laquelle la pente négative est

supérieure à une valeur absolue de 1,0.

20. Méthode selon la revendication 5 ou selon une quelconque revendication dépendant de celle-ci, dans laquelle le second polymère est un polyuréthane, une polyfluoropolyoléfine ou un composant élastomère mélangé dans du polypropylène.

21. Moule pour former un cathéter intégral en une pièce (2) ayant un tube (4) et un raccord (6), comprenant :

une cavité de moule avec :
une partie de tube (255), dont l'extrémité distale est biseautée ;
une partie de raccord (270) s'étendant à partir de la partie de tube ; et
une partie de connecteur à l'extrémité proximale de la partie de raccord ;
une ouverture dans la cavité de moule pour recevoir un premier polymère fondu destiné à être injecté dans la partie de raccord et un second polymère fondu destiné à être injecté dans la partie de tube ; et
un seuil dans la cavité de moule par lequel un fluide sous pression peut être injecté à l'intérieur de la cavité de moule.

22. Moule selon la revendication 21, dans lequel la partie de connecteur est un verrou mâle ou un verrou femelle.

23. Moule selon la revendication 21, dans lequel le rapport d'aspect est supérieur à 200.

24. Moule selon la revendication 21, dans lequel la partie de connecteur est de forme sensiblement cylindrique.

25. Moule selon la revendication 21, dans lequel l'orifice est situé dans au moins une partie parmi la partie de raccord et la partie de tube de la cavité.

26. Moule selon la revendication 21, dans lequel une partie de raccord qui est formée à partir de la partie de raccord de la cavité de moule est tournée par un rotateur couplé dans le moule depuis une première position jusqu'à une seconde position ; et la partie de raccord est fixée à un second moule.

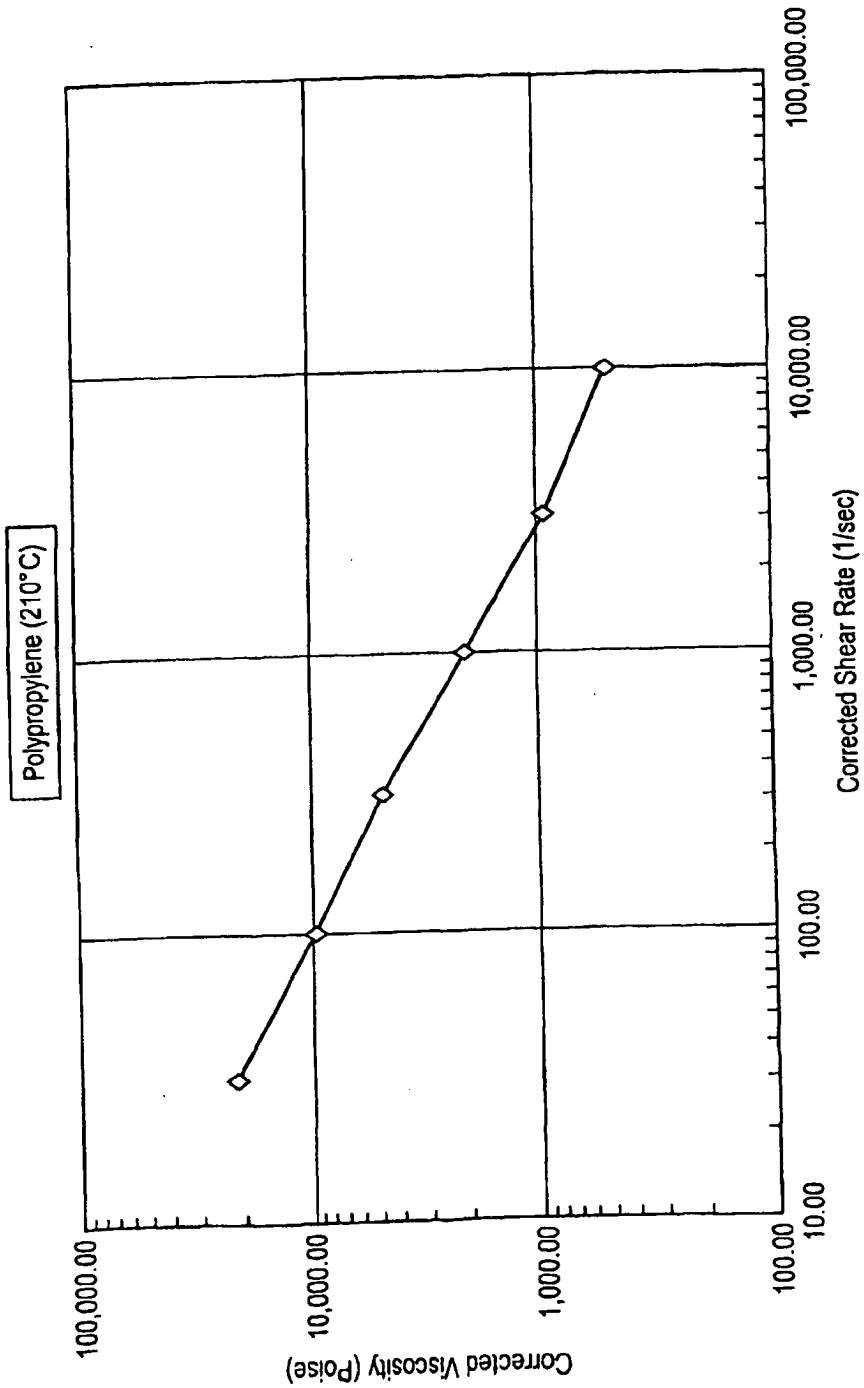

Polypropylene (210°C)
Corrected Viscosity (Poise)
100,000.00
10,000.00
1,000.00
100.00
10.00
Corrected Shear Rate (1/sec)
100.00
1,000.00
10,000.00
100,000.00

FIG. 1

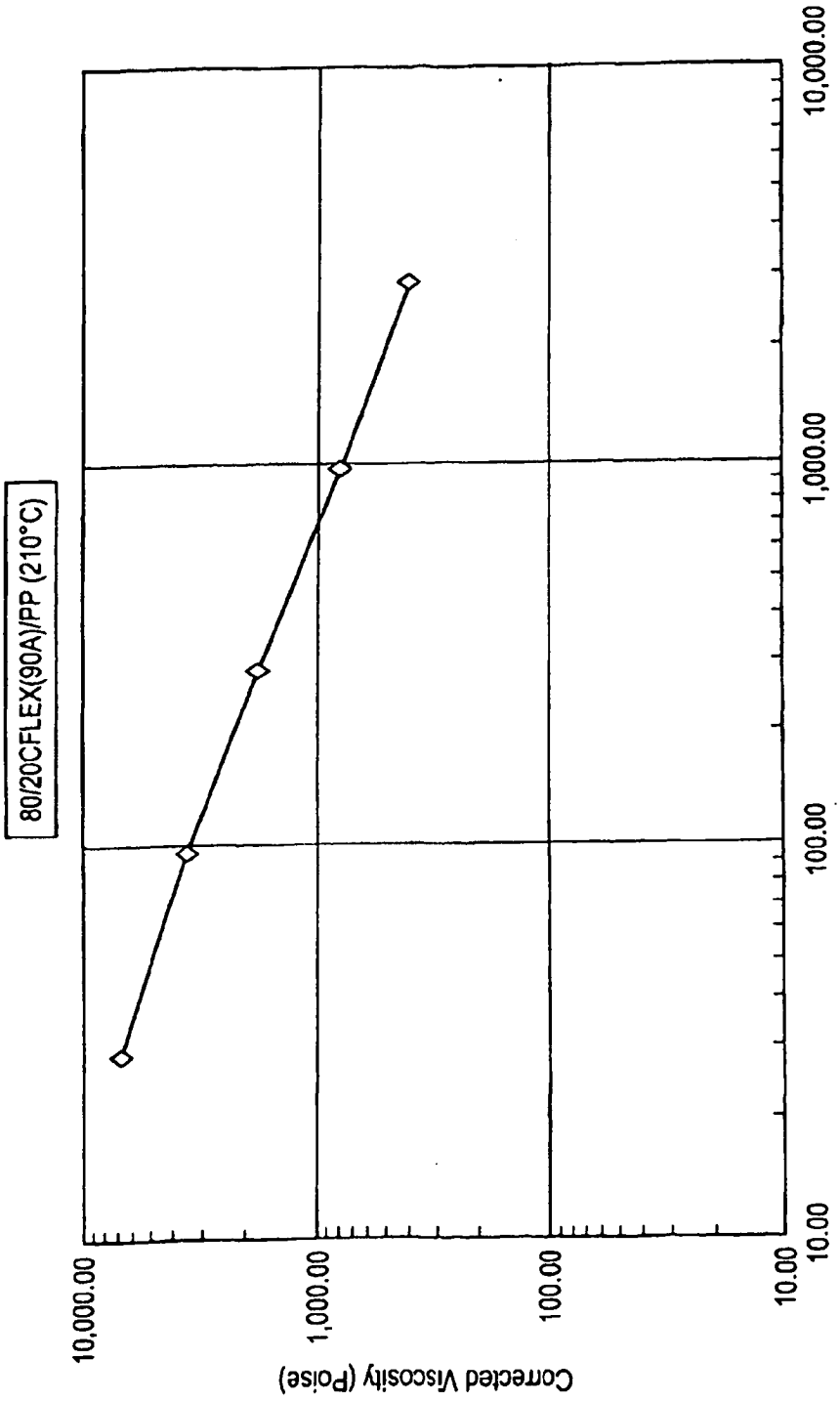
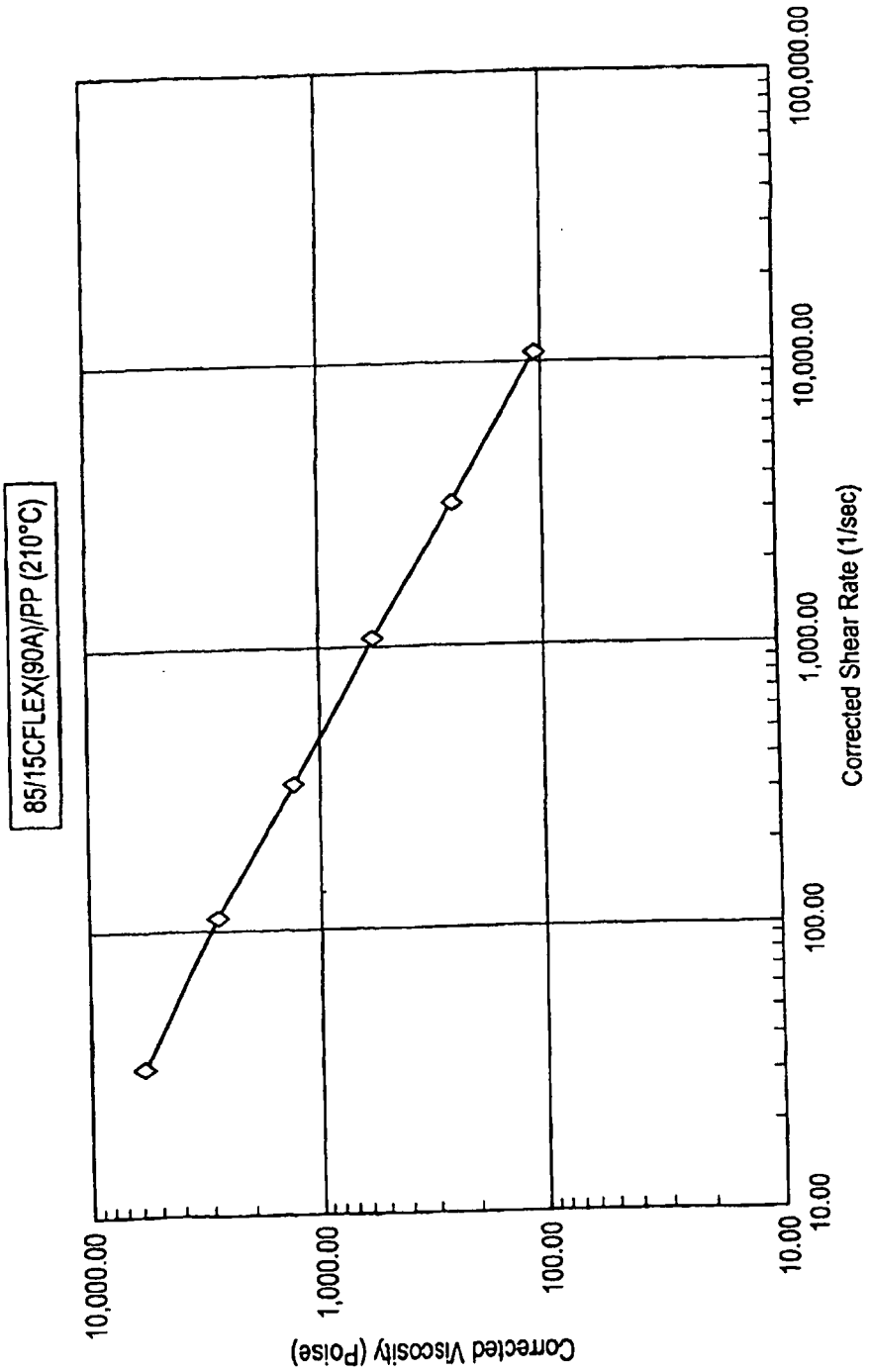

80/20CFLEX(90A)/PP (210°C)
Corrected Viscosity (Poise)
10,000.00
1,000.00
100.00
10.00
10.00
100.00
1,000.00
10,000.00
Corrected Shear Rate (1/sec)

FIG. 2


85/15CFLEX(90A)/PP (210°C)
Corrected Viscosity (Poise)
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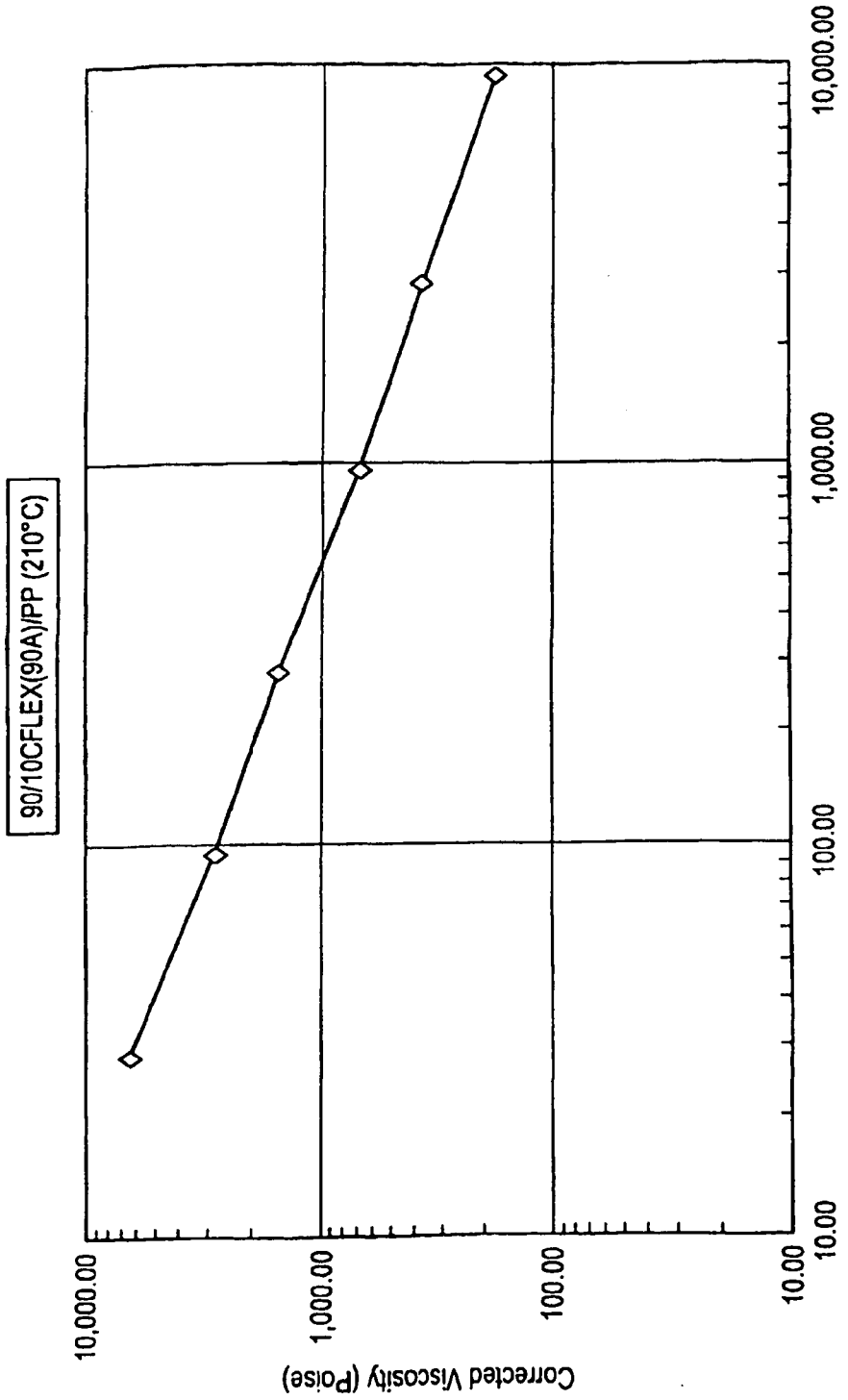
1,000.00
100.00
10.00
10.00
100.00
1,000.00
10,000.00
100,000.00
Corrected Shear Rate (1/sec)

FIG. 3


90/10CFLEX(90A)/PP (210°C)
Corrected Viscosity (Poise)
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10.00
10.00
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1,000.00
10,000.00
Corrected Shear Rate (1/sec)

FIG. 4

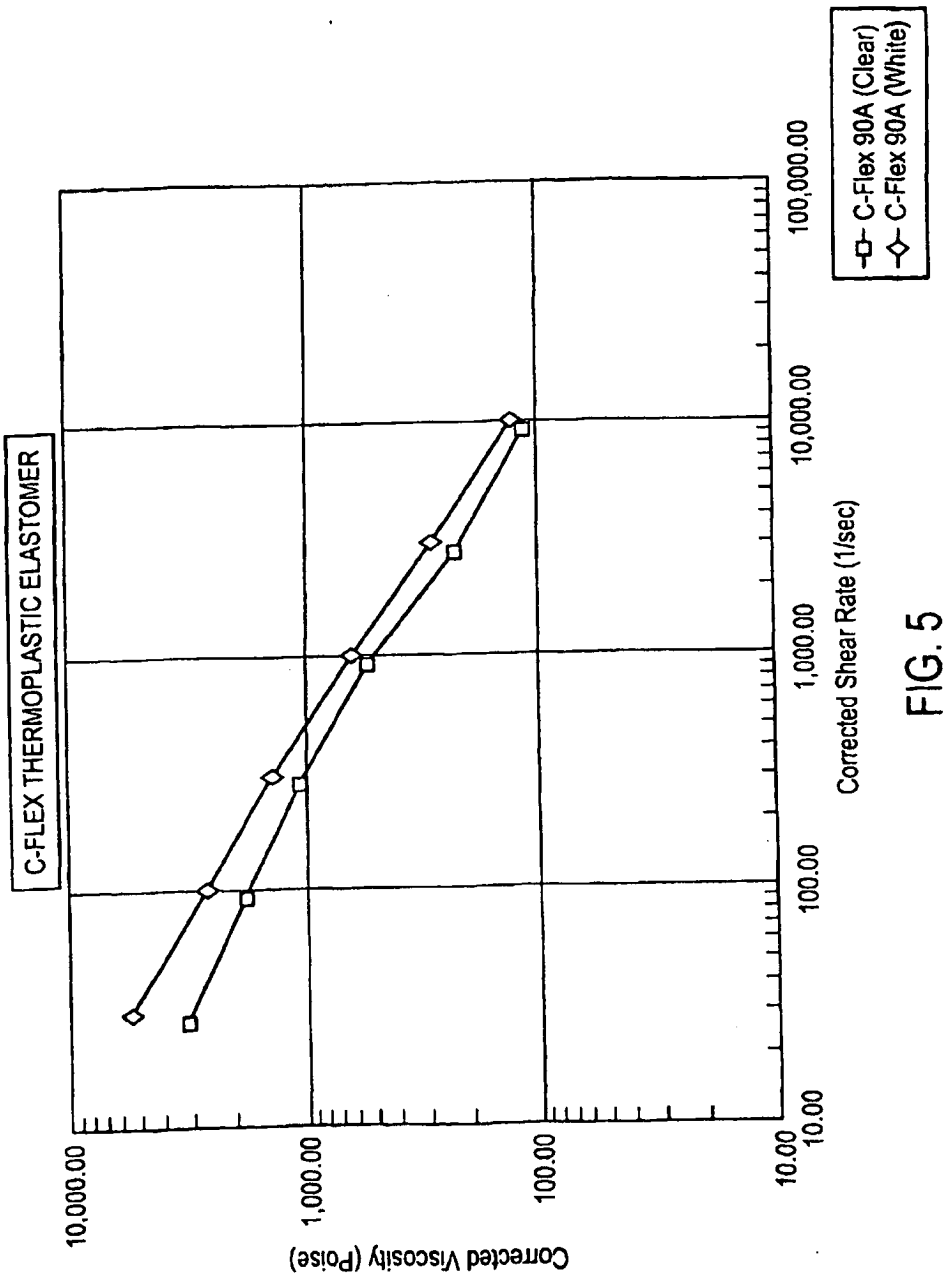
C-FLEX THERMOPLASTIC ELASTOMER
Corrected Viscosity (Poise)
10,000.00
1,000.00
100.00
10.00
10.00
100.00
1,000.00
10,000.00
100,000.00
Corrected Shear Rate (1/sec)
C-Flex 90A (Clear)
C-Flex 90A (White)

FIG. 5

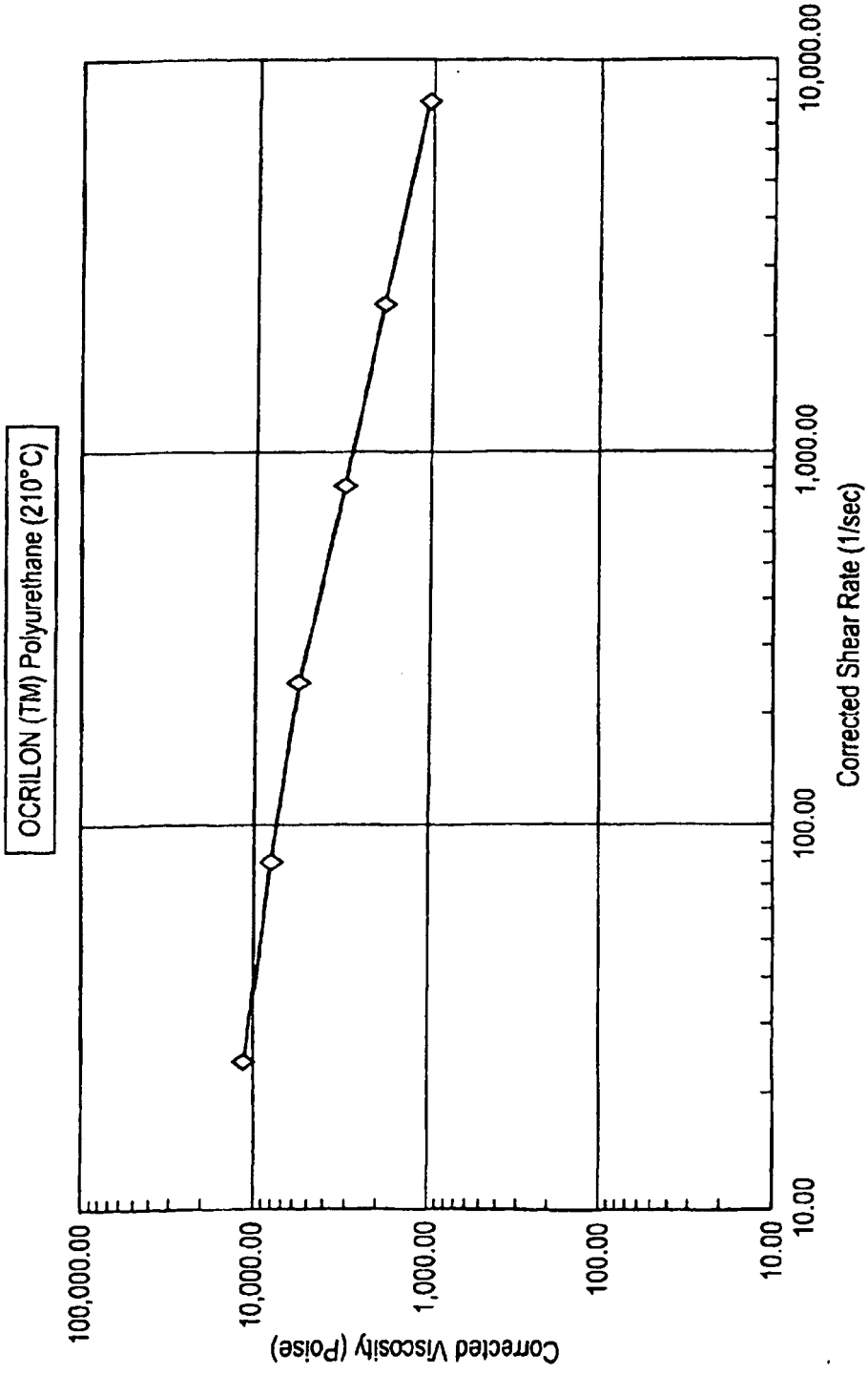
OCRILON (TM) Polyurethane (210°C)
Corrected Viscosity (Poise)
100,000.00
10,000.00
1,000.00
100.00
10.00
Corrected Shear Rate (1/sec)
10.00
100.00
1,000.00
10,000.00

FIG. 6

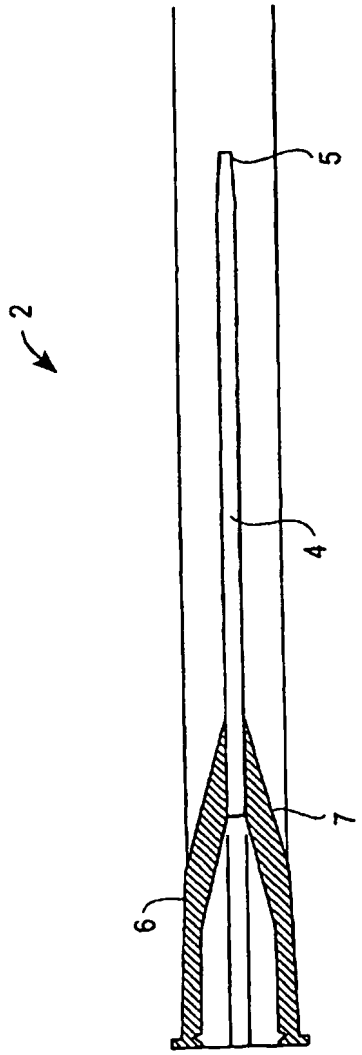

FIG. 7

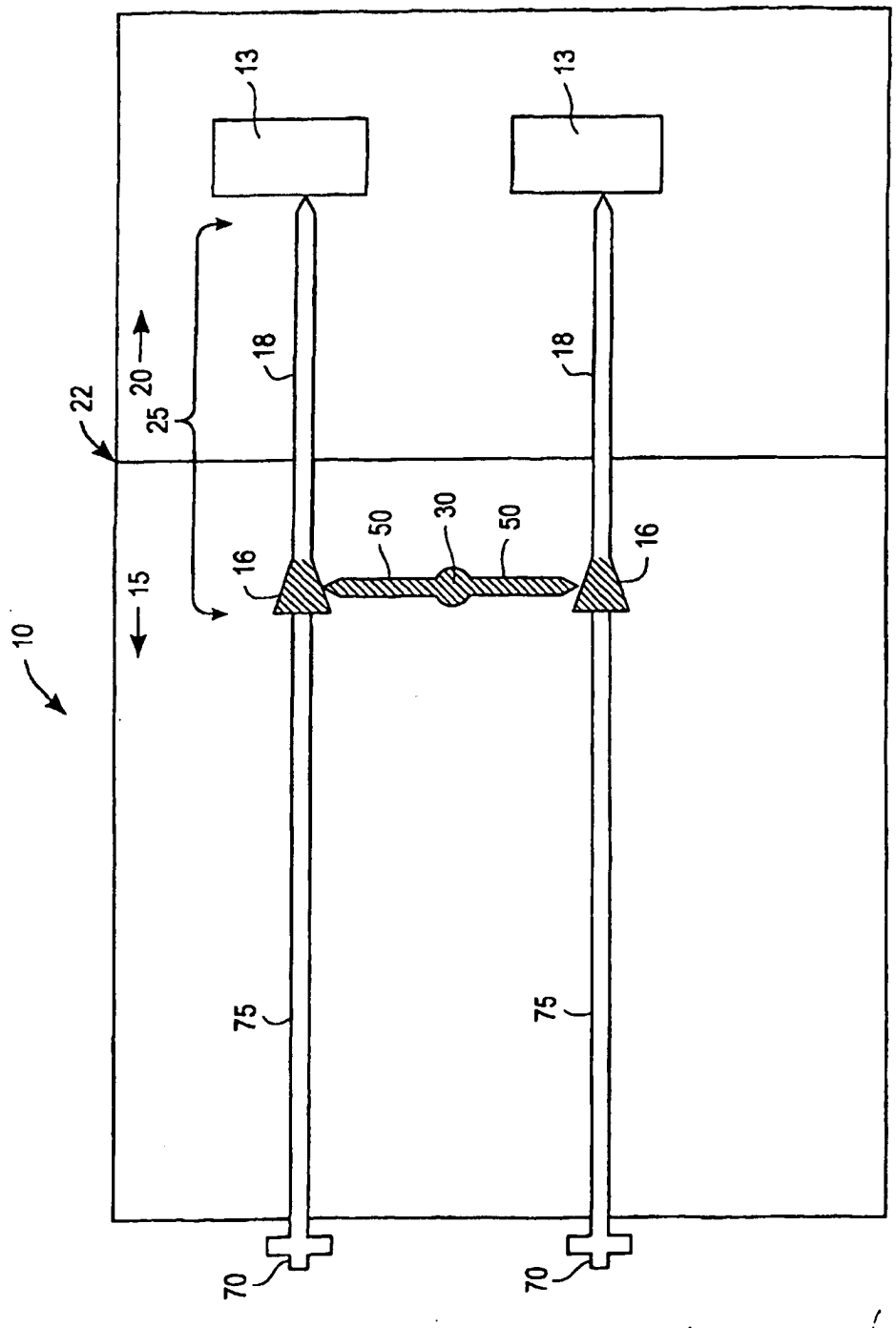

FIG. 8

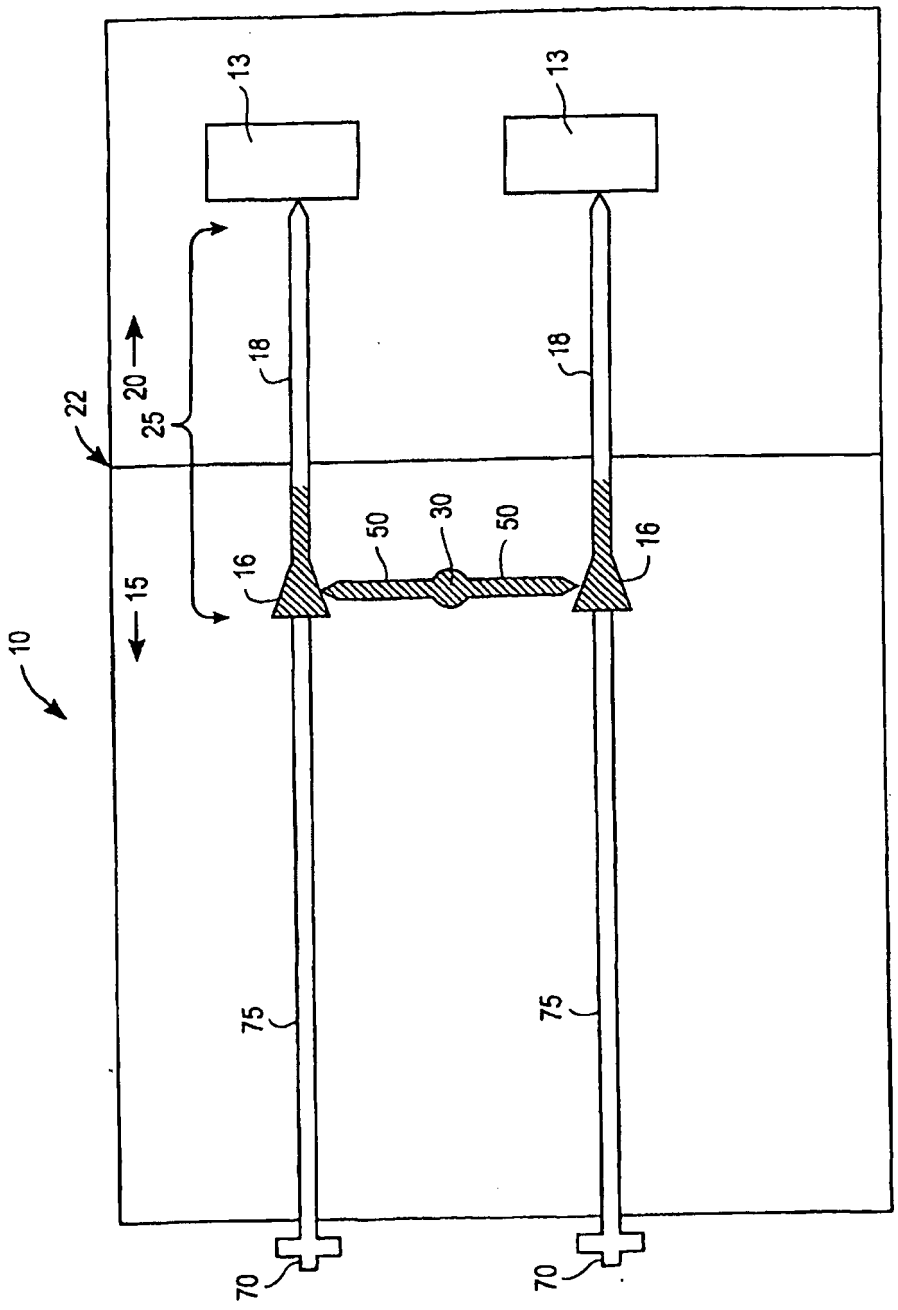

FIG. 9

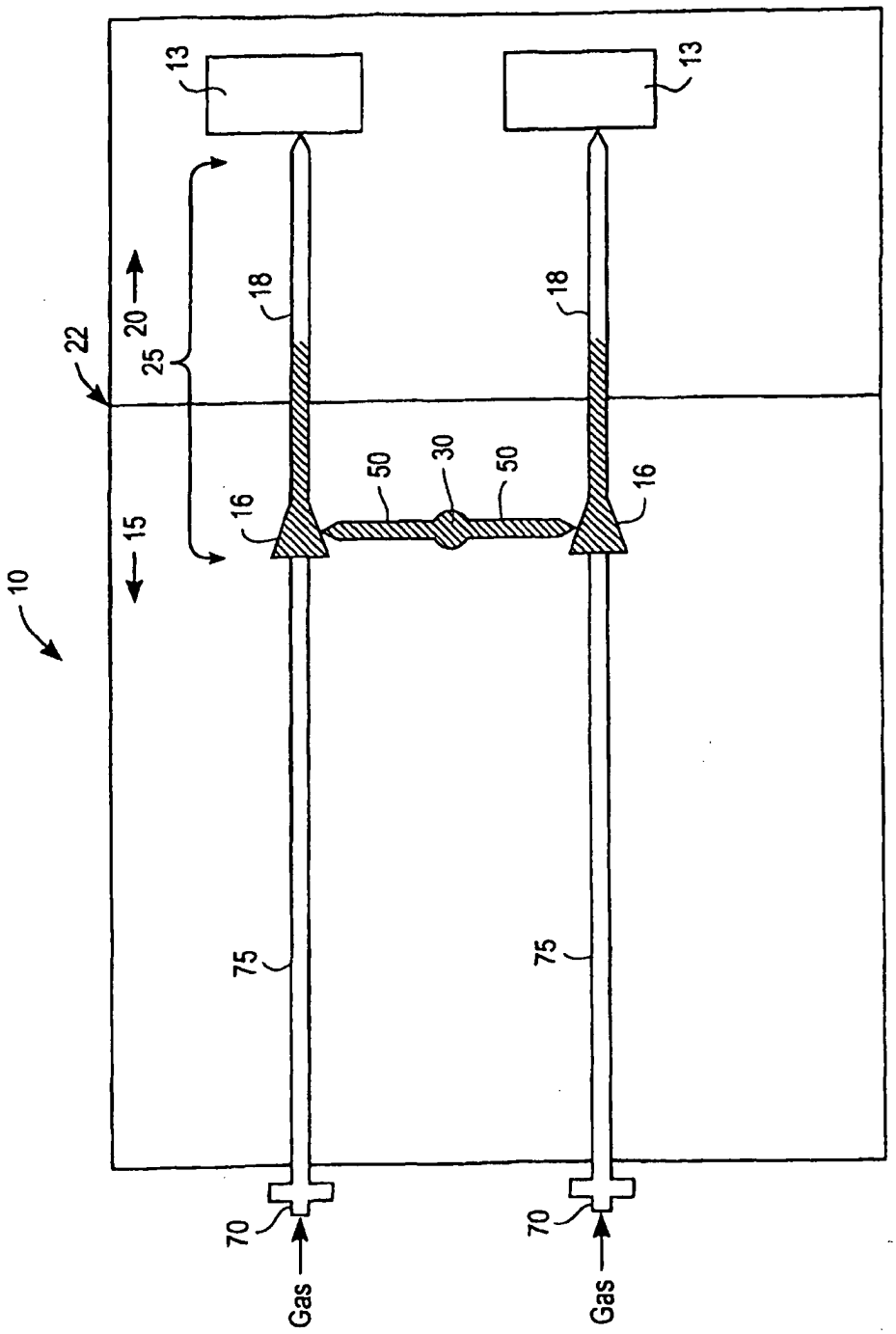

FIG. 10

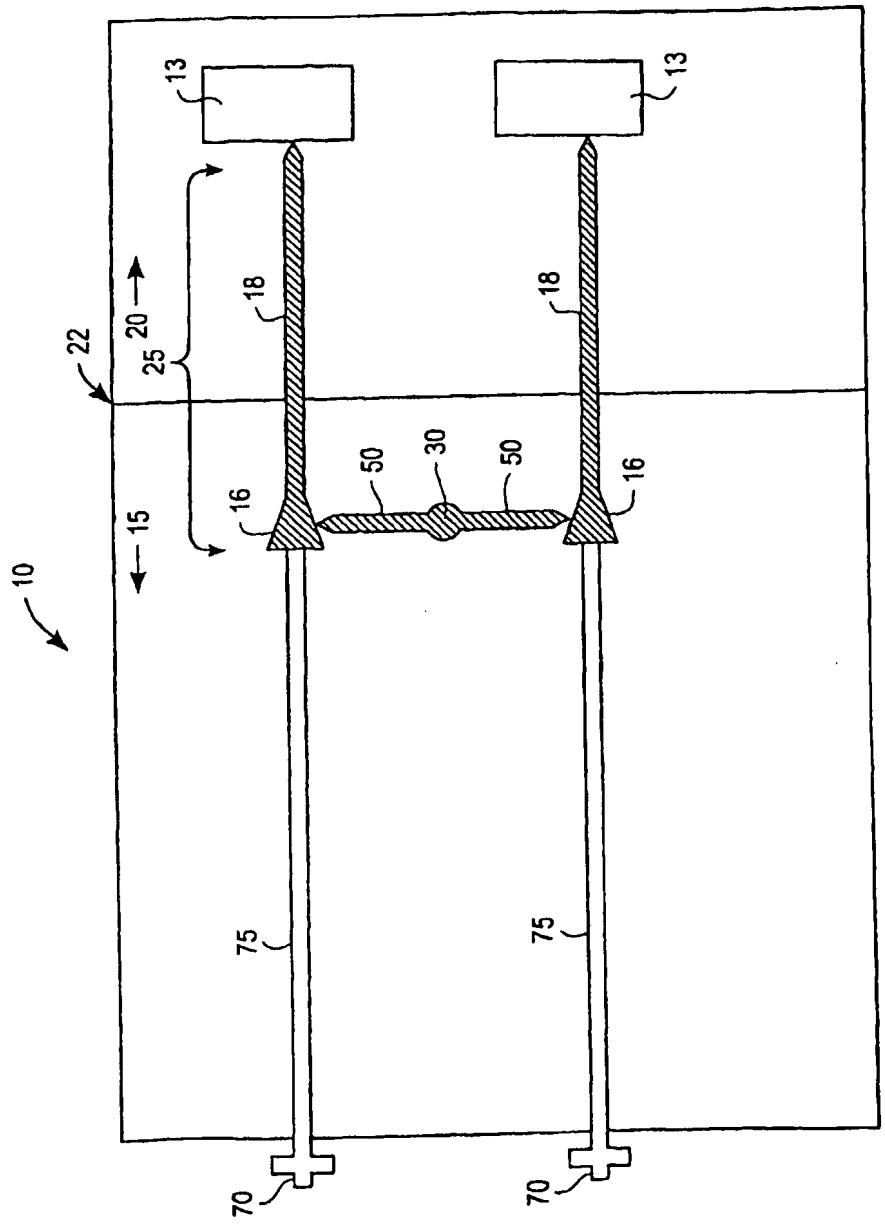

FIG. 11

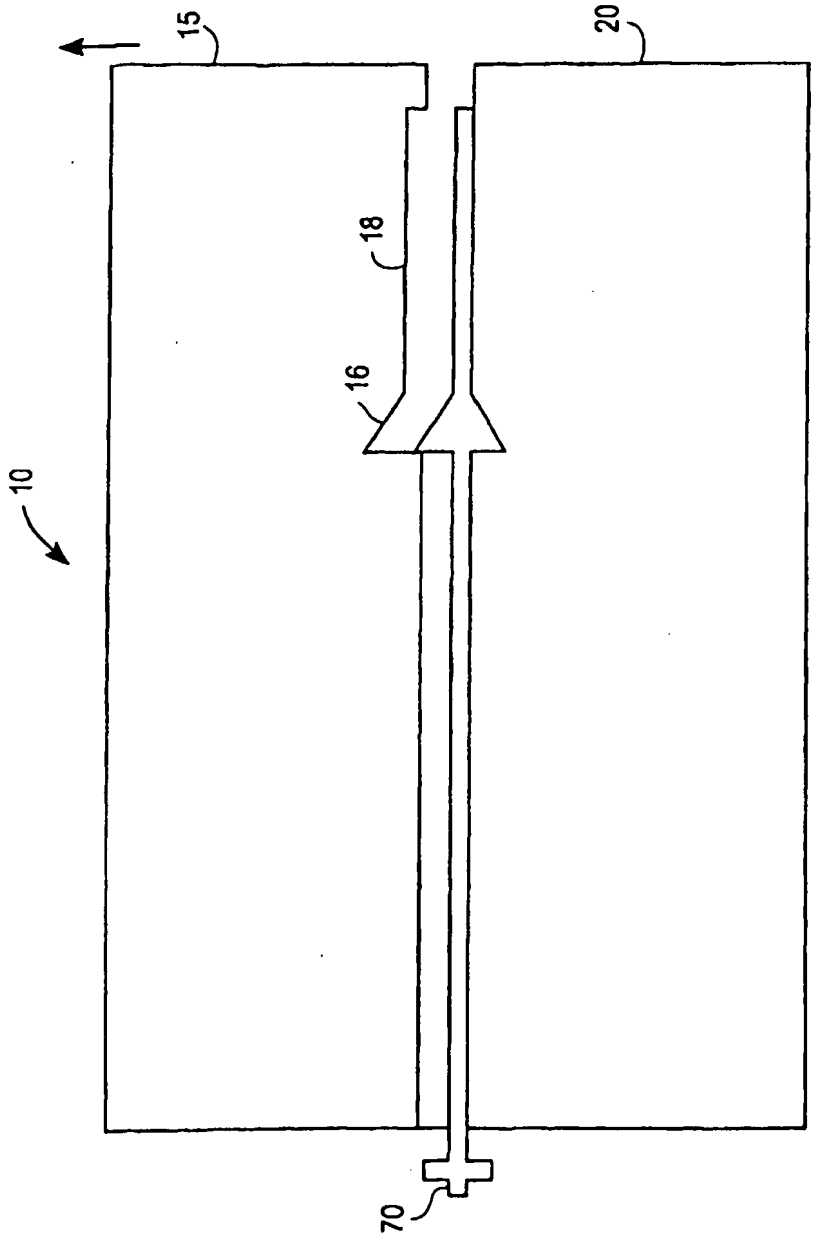

FIG. 12

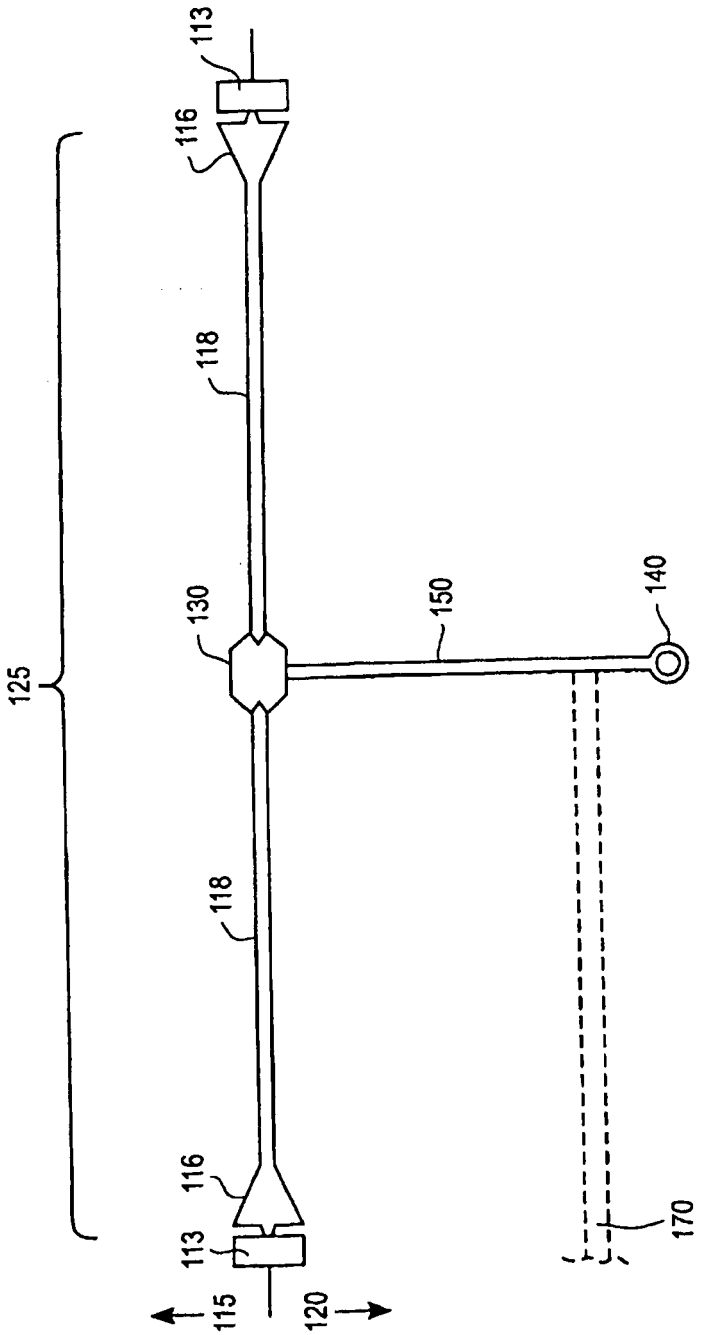

FIG. 13

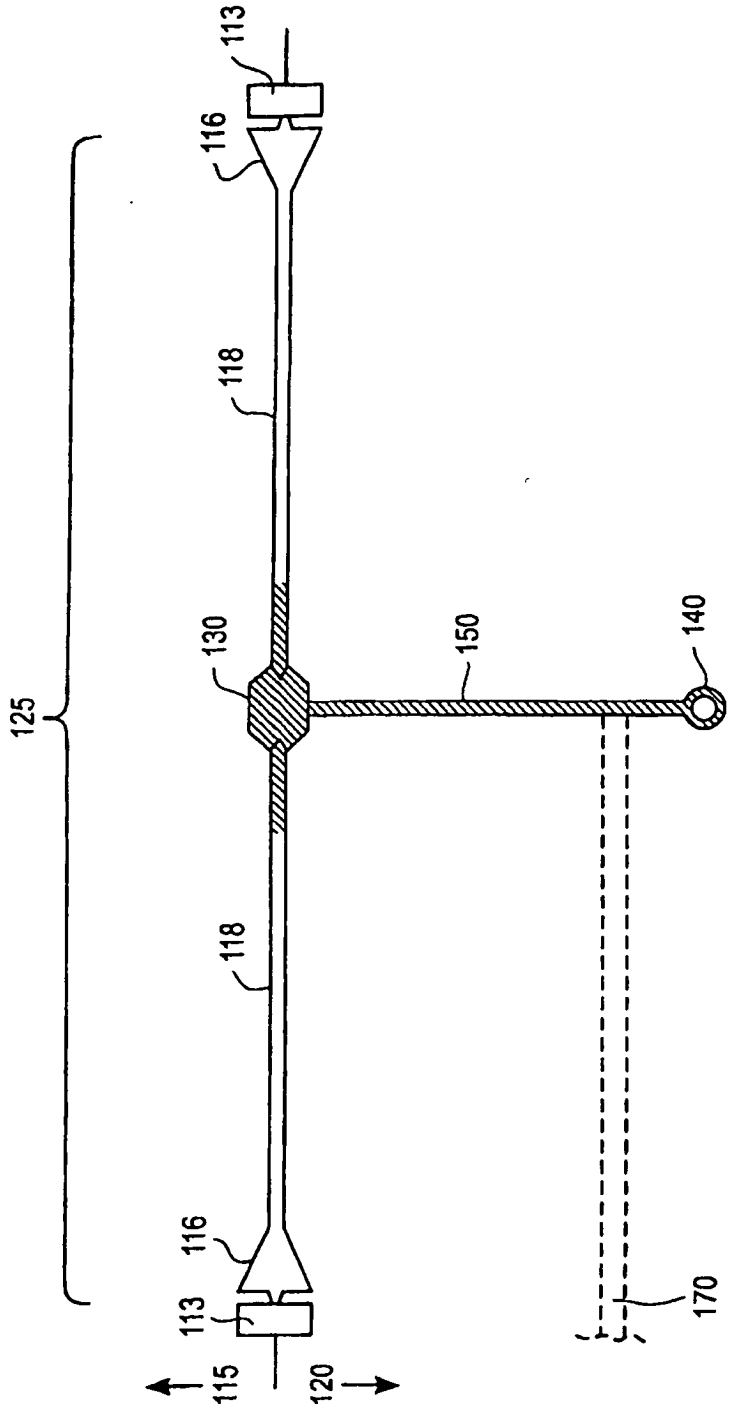

FIG. 14

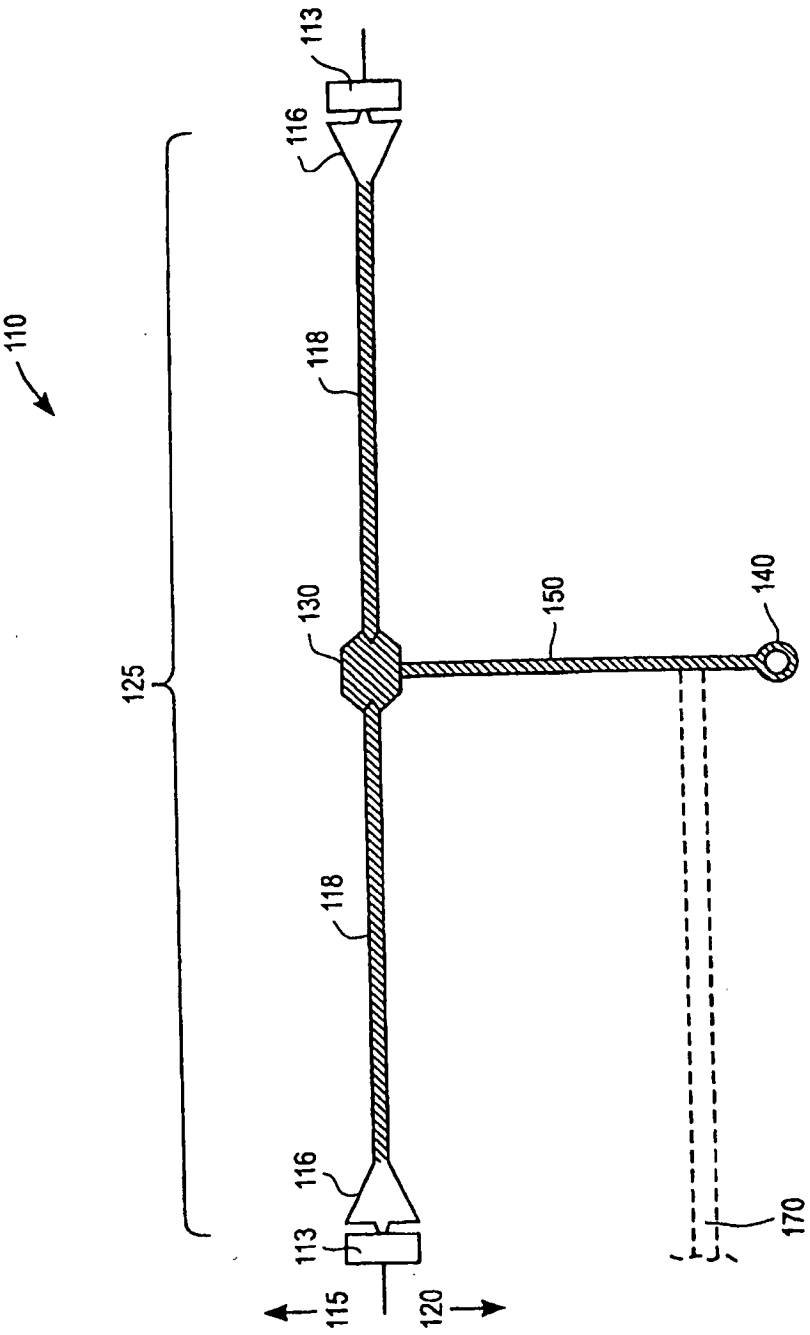

FIG. 15

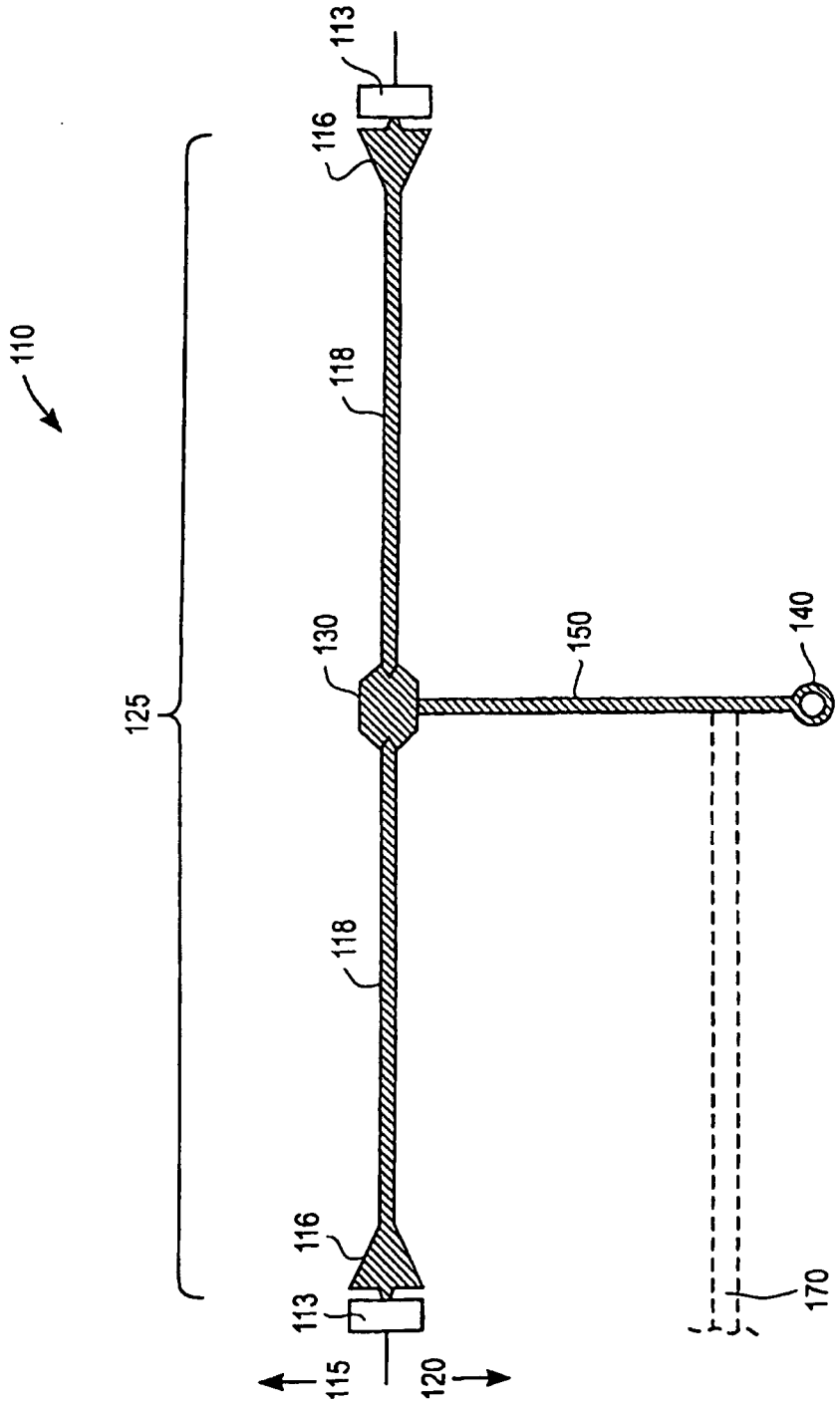

FIG. 16

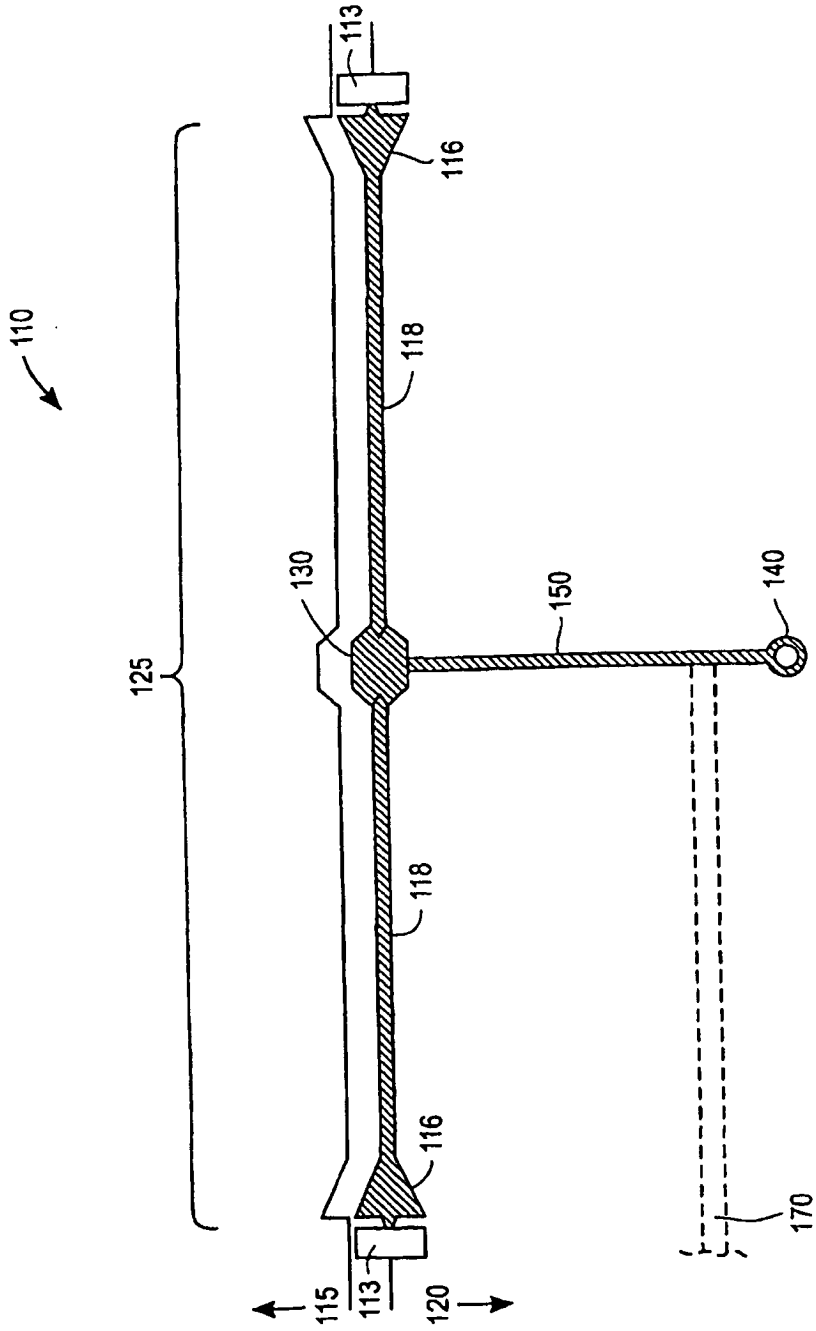

FIG. 17

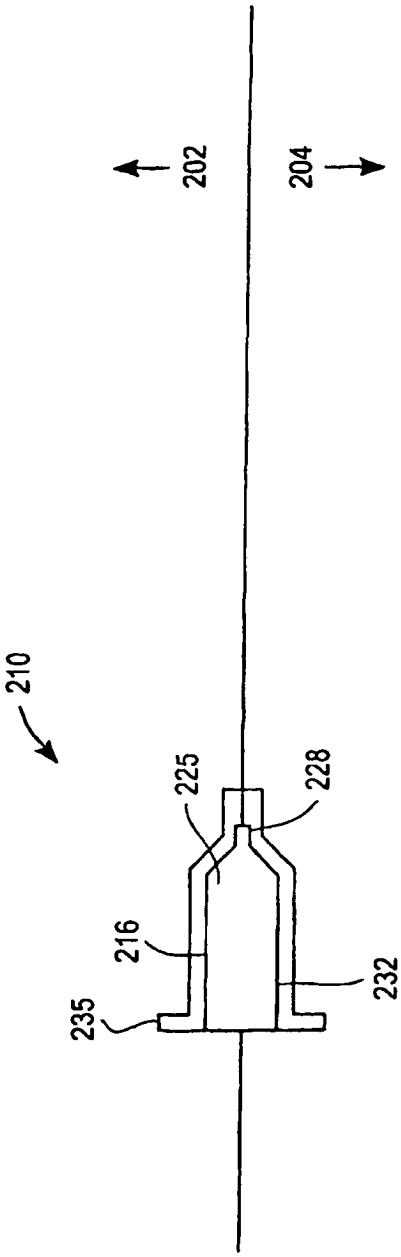

FIG. 18

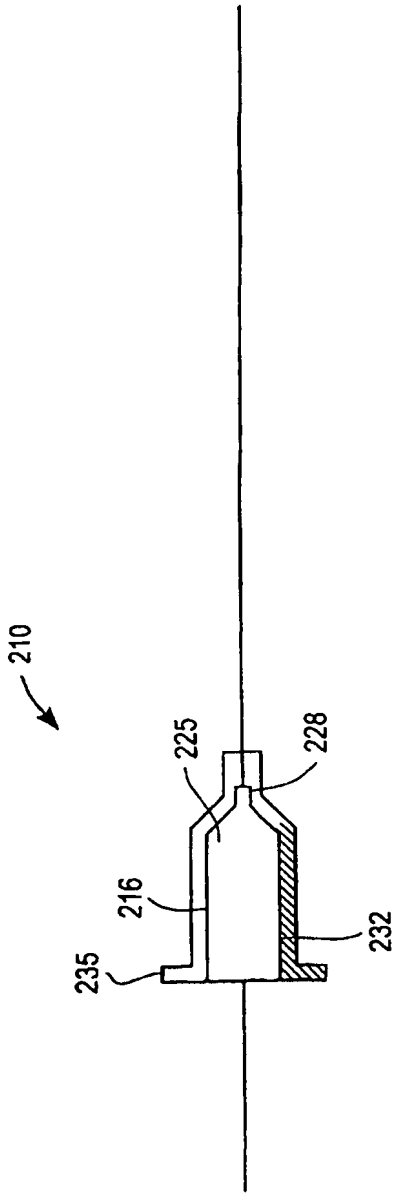

FIG. 19

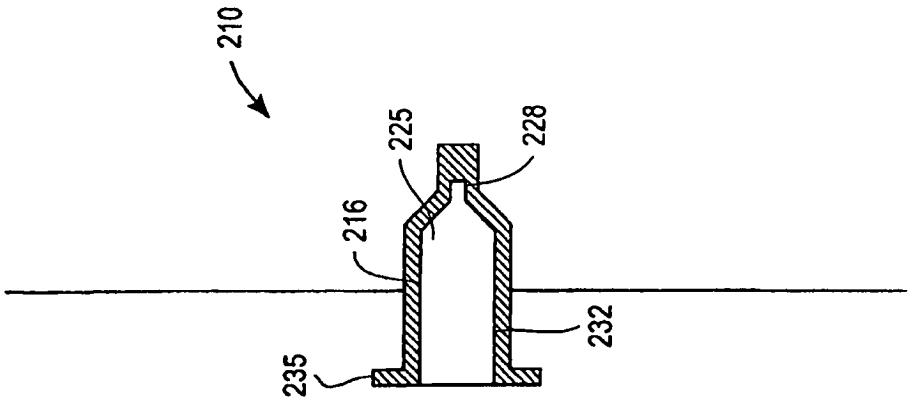

FIG. 20

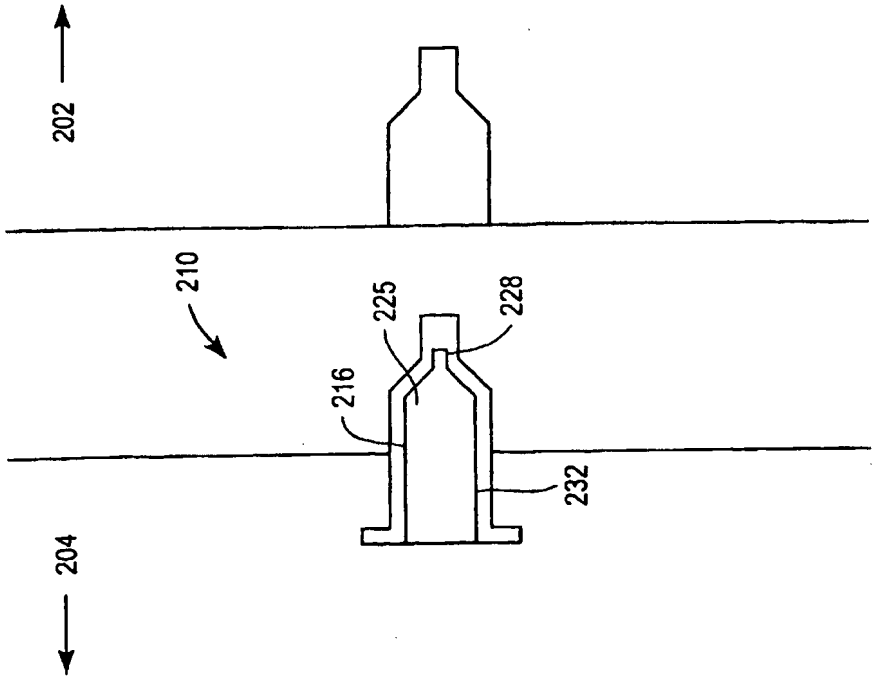

FIG. 21

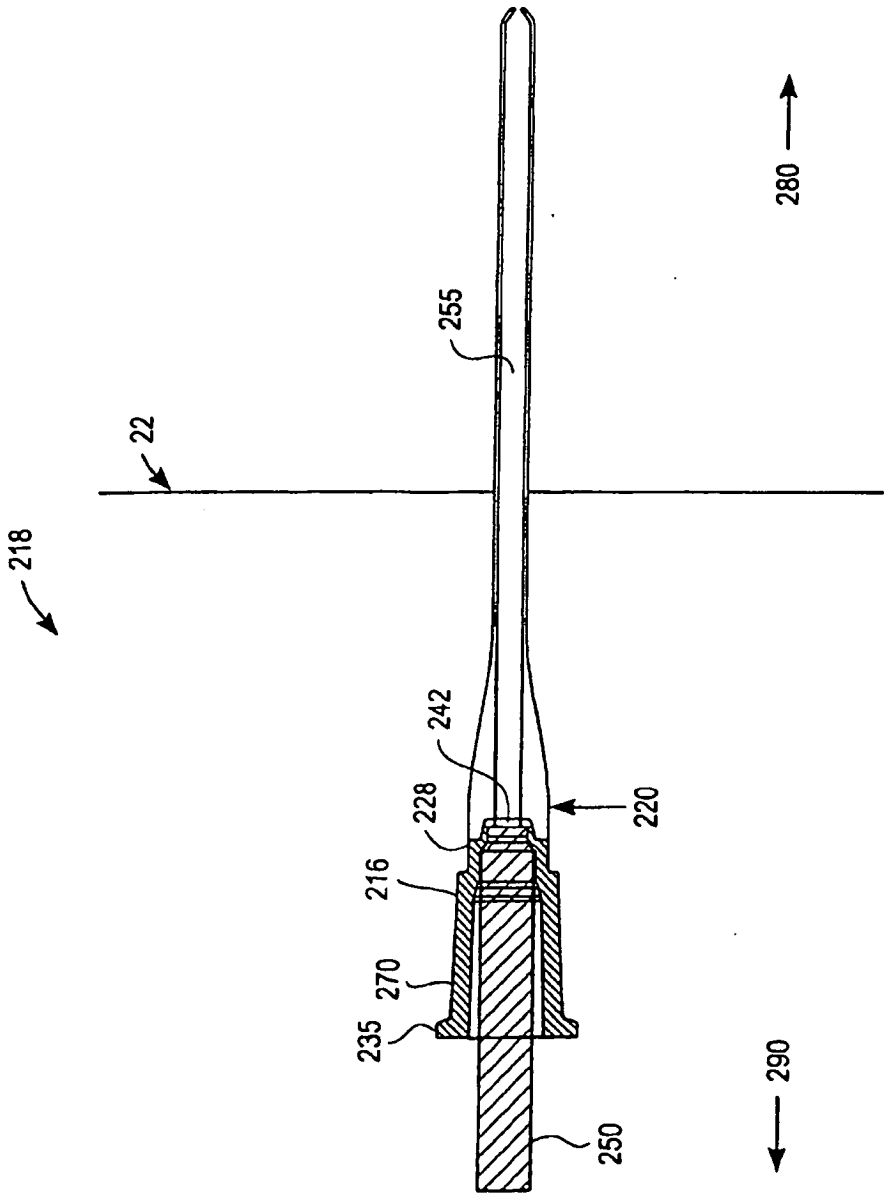

FIG. 22

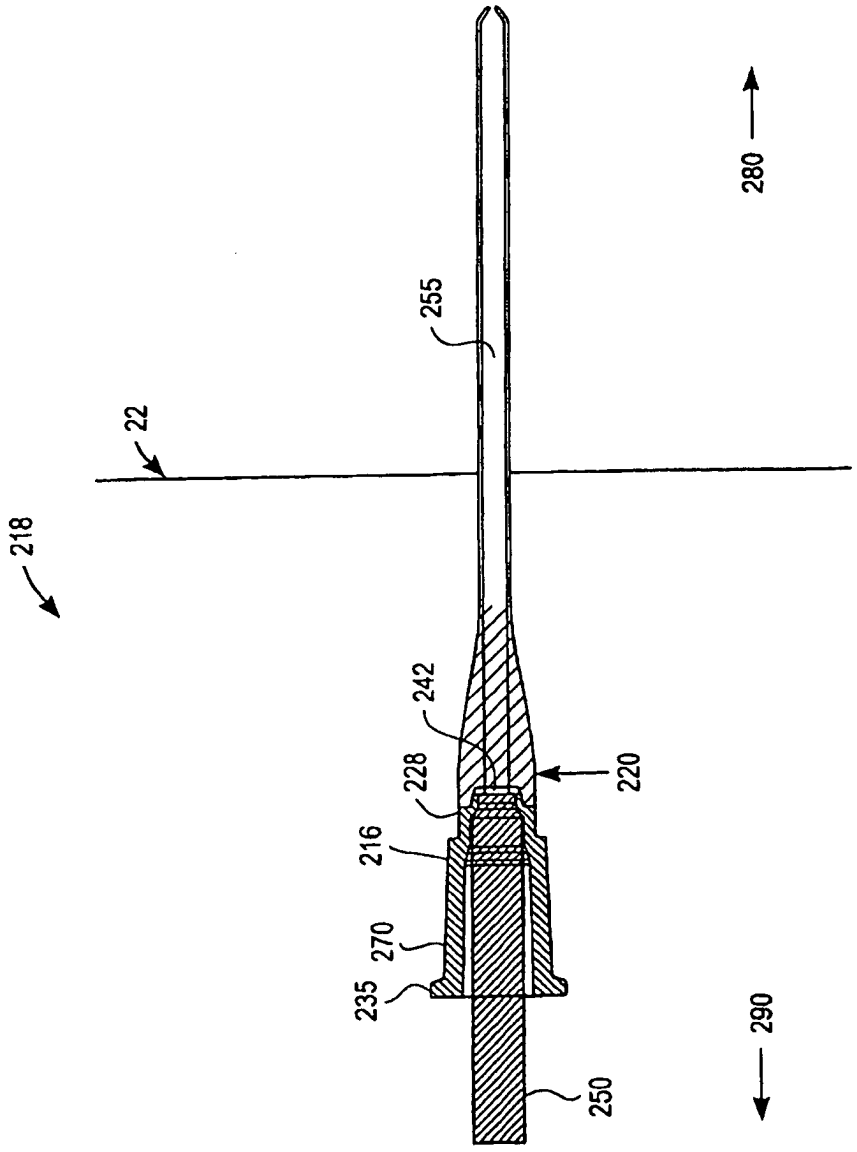

FIG. 23

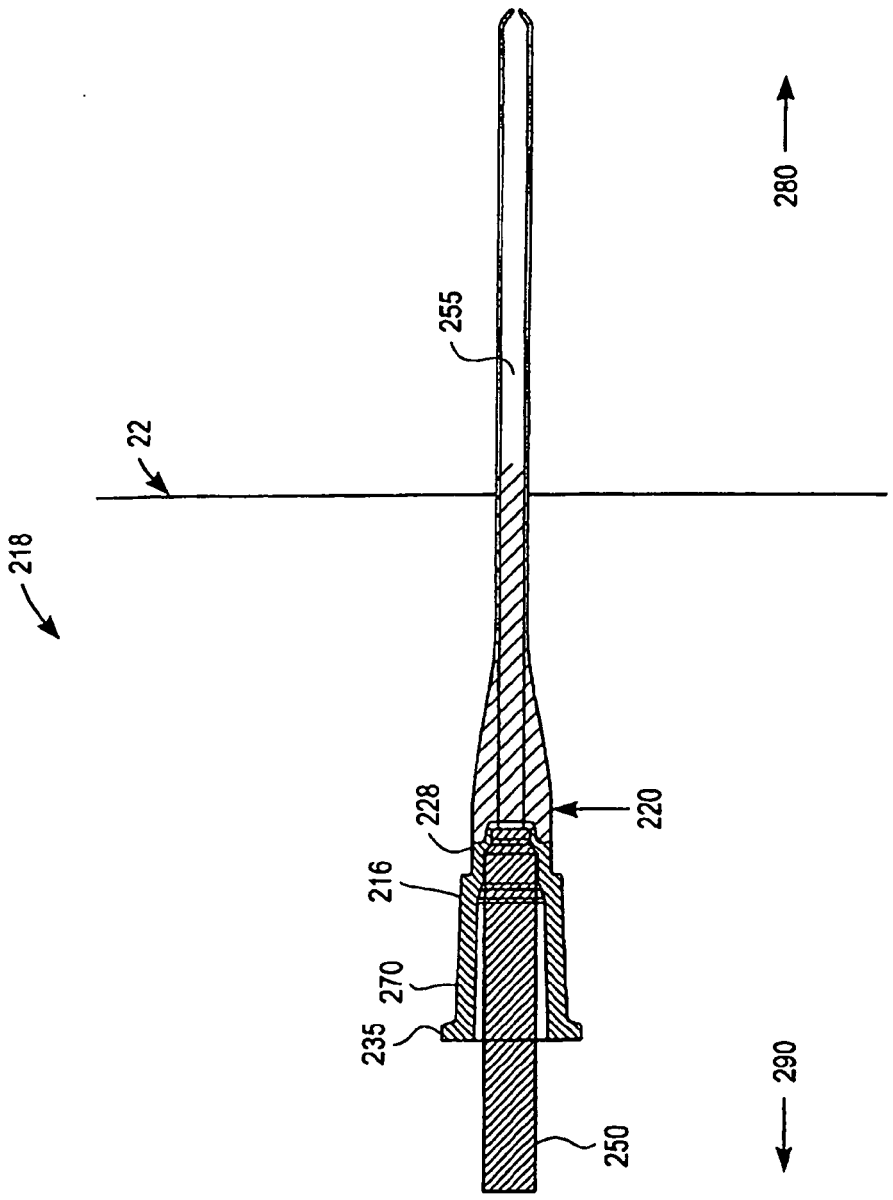

FIG. 24

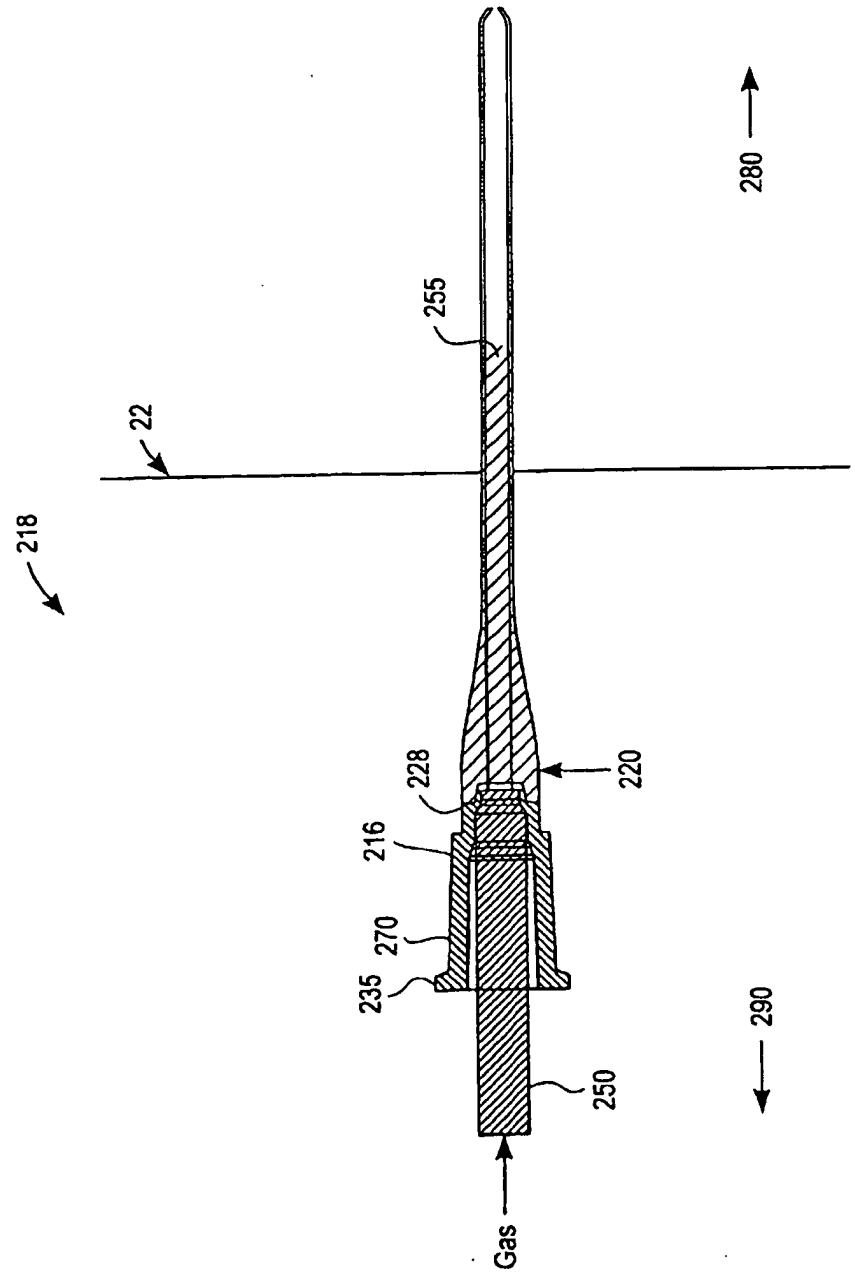

FIG. 25

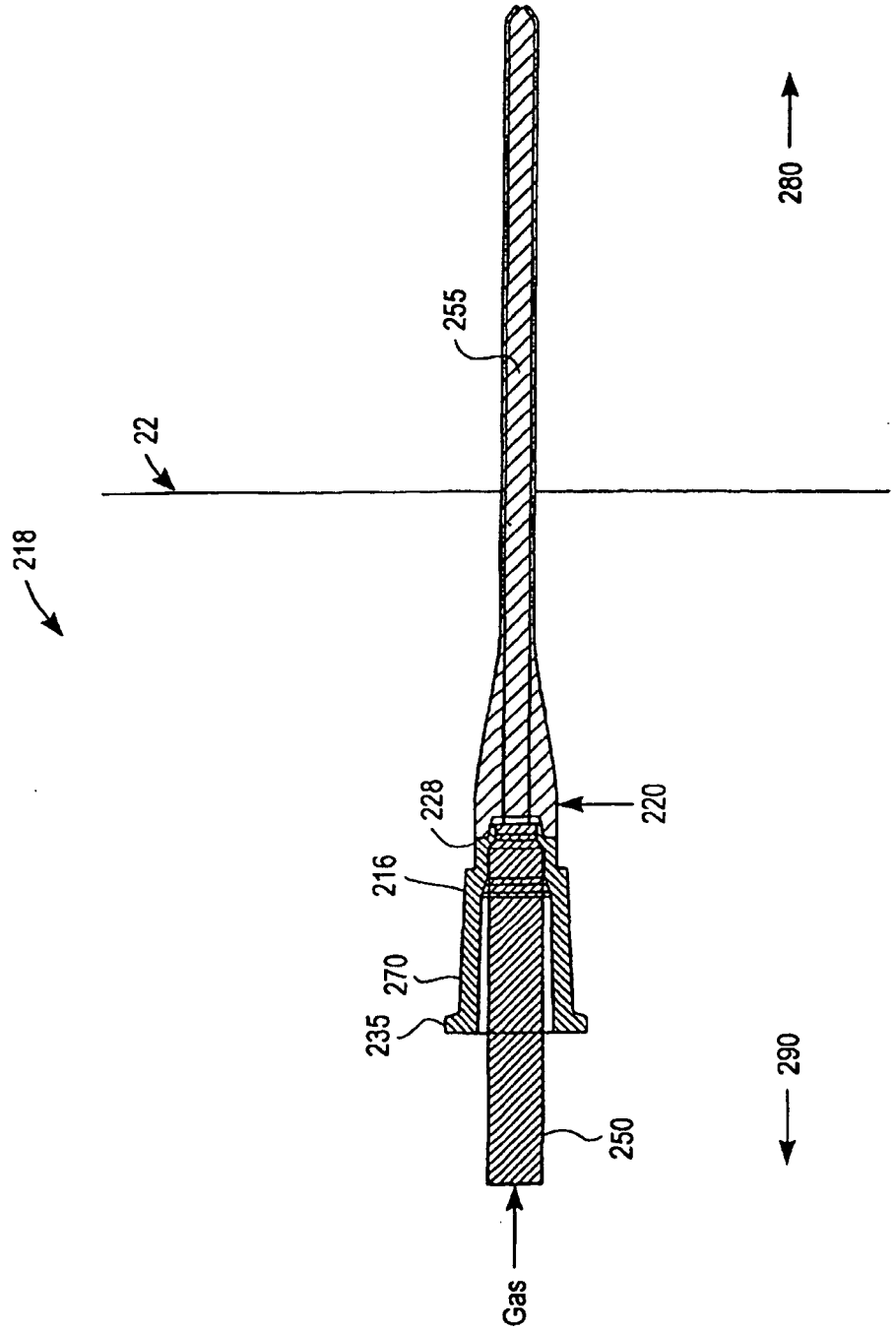

FIG. 26

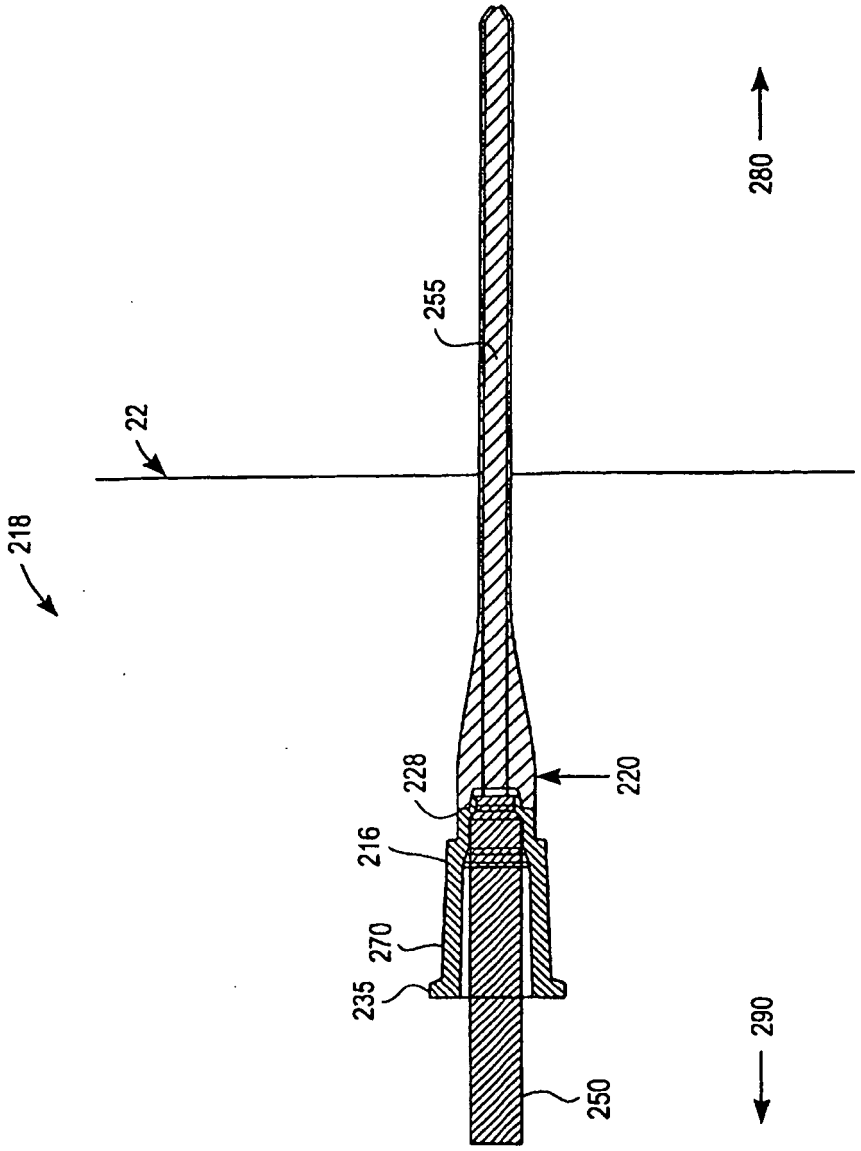

FIG. 27

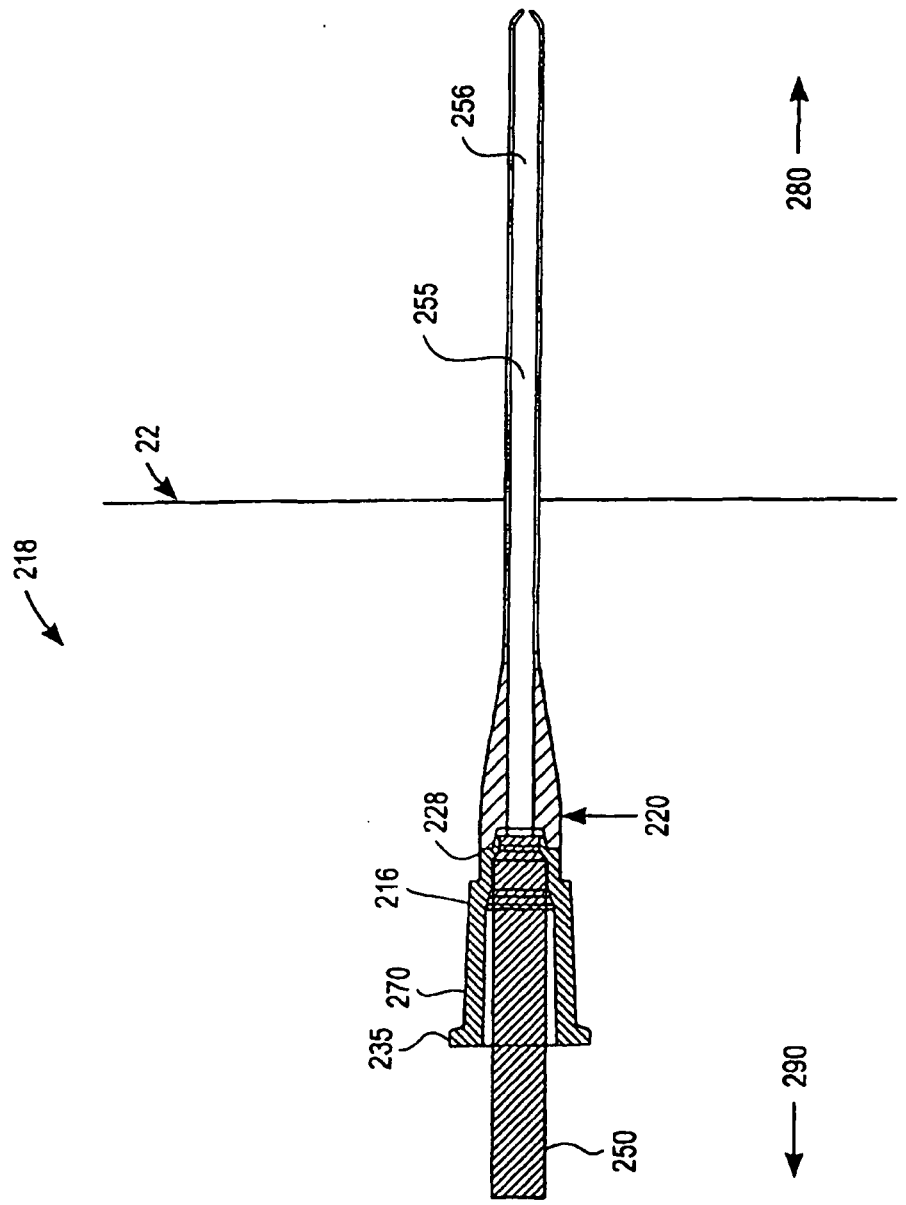

FIG. 28

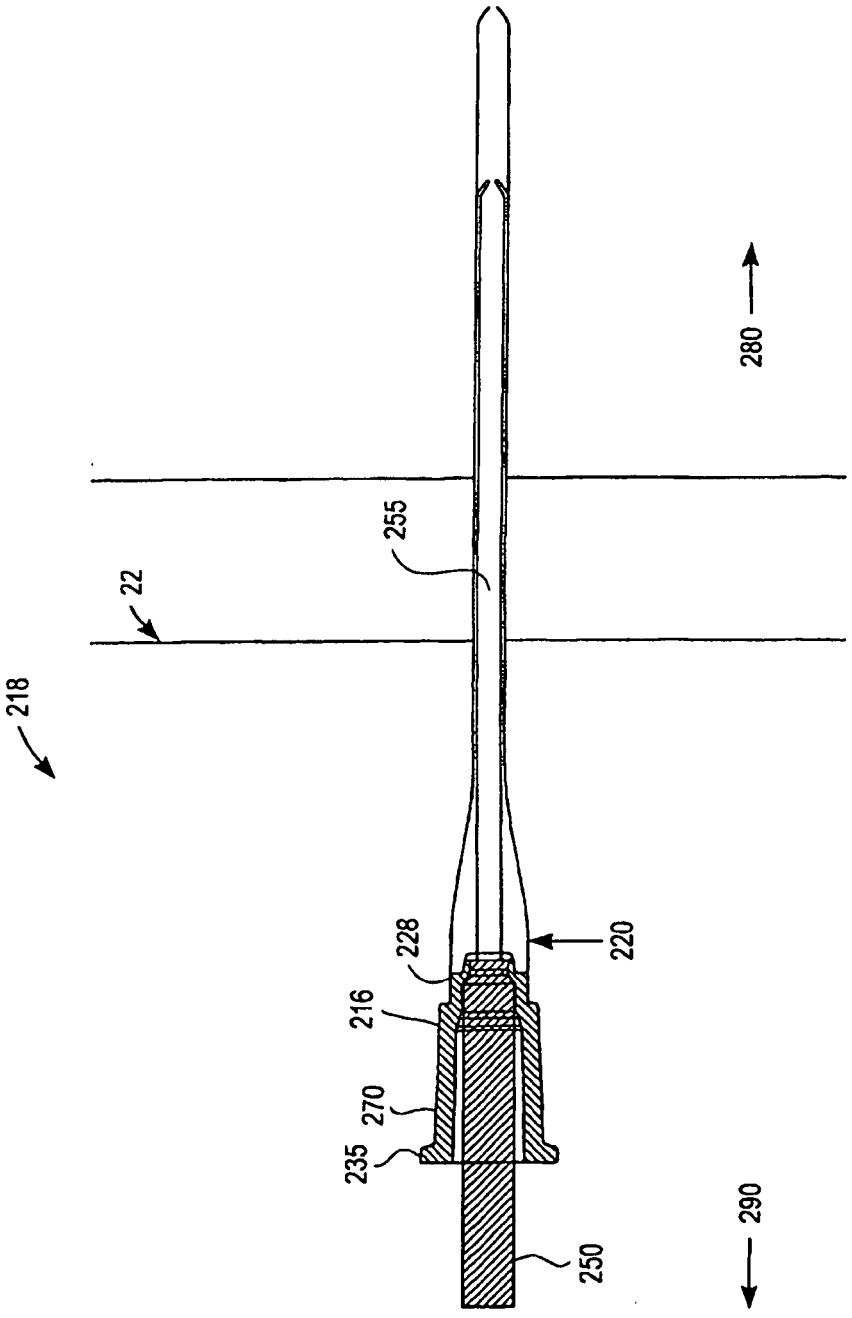

FIG. 29

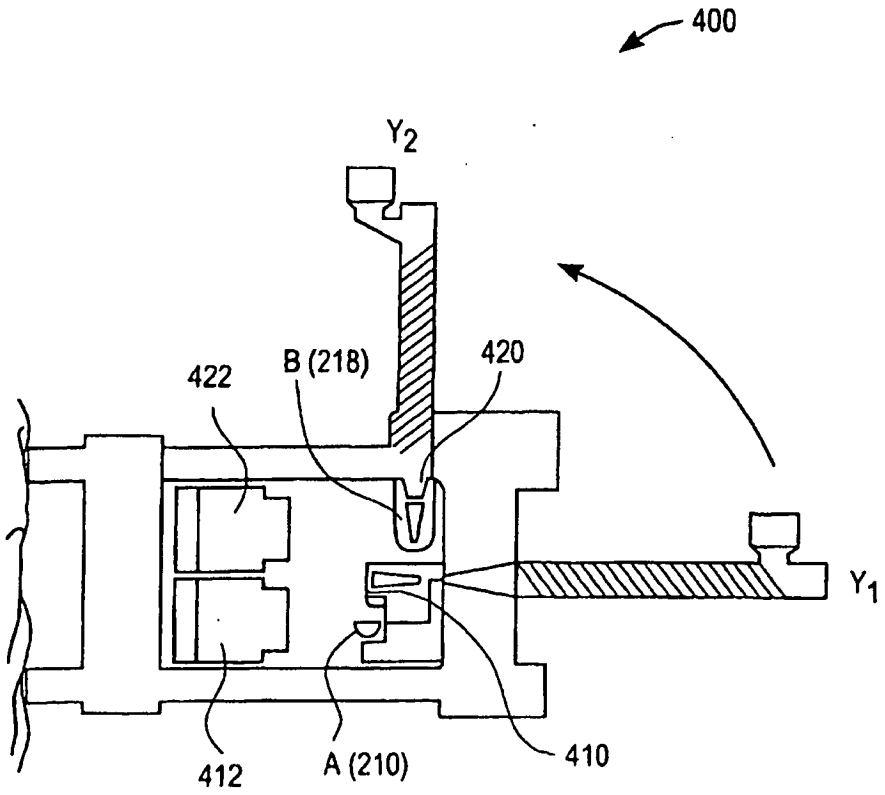

FIG. 30

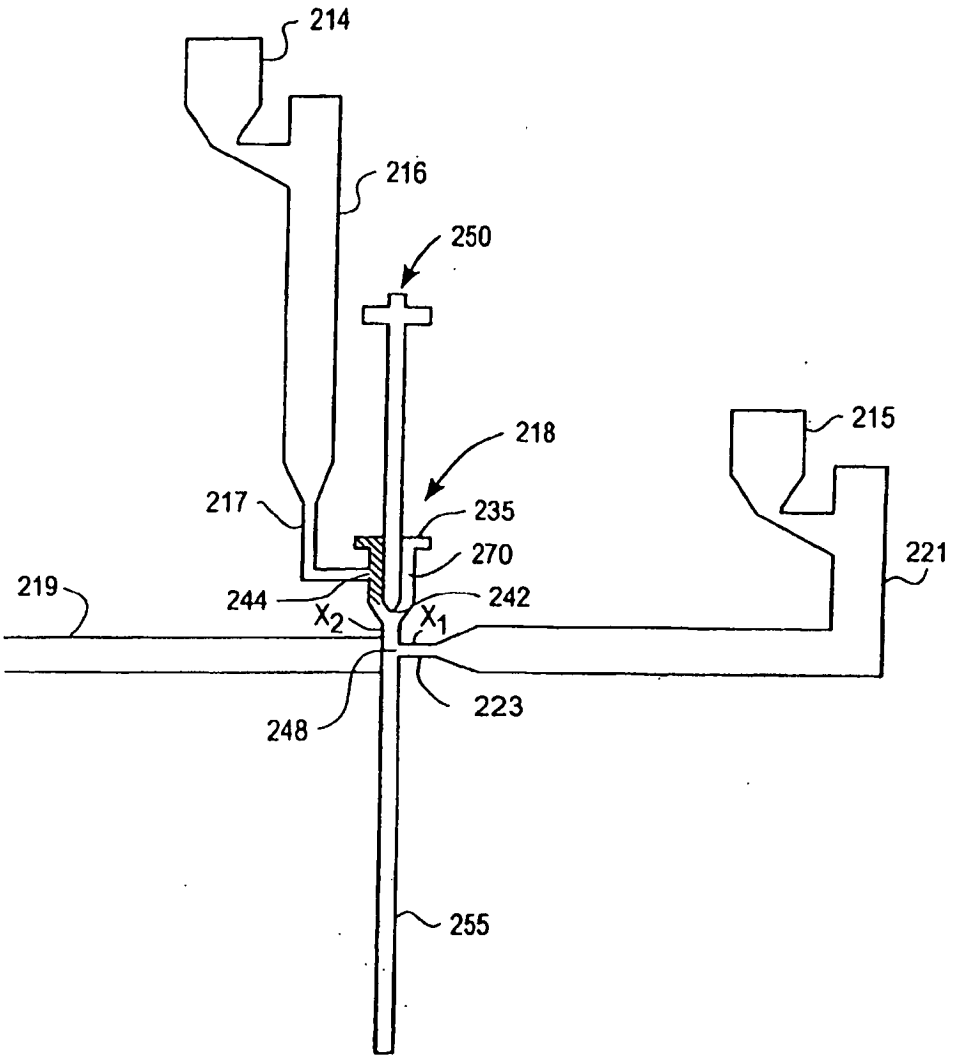

FIG. 31

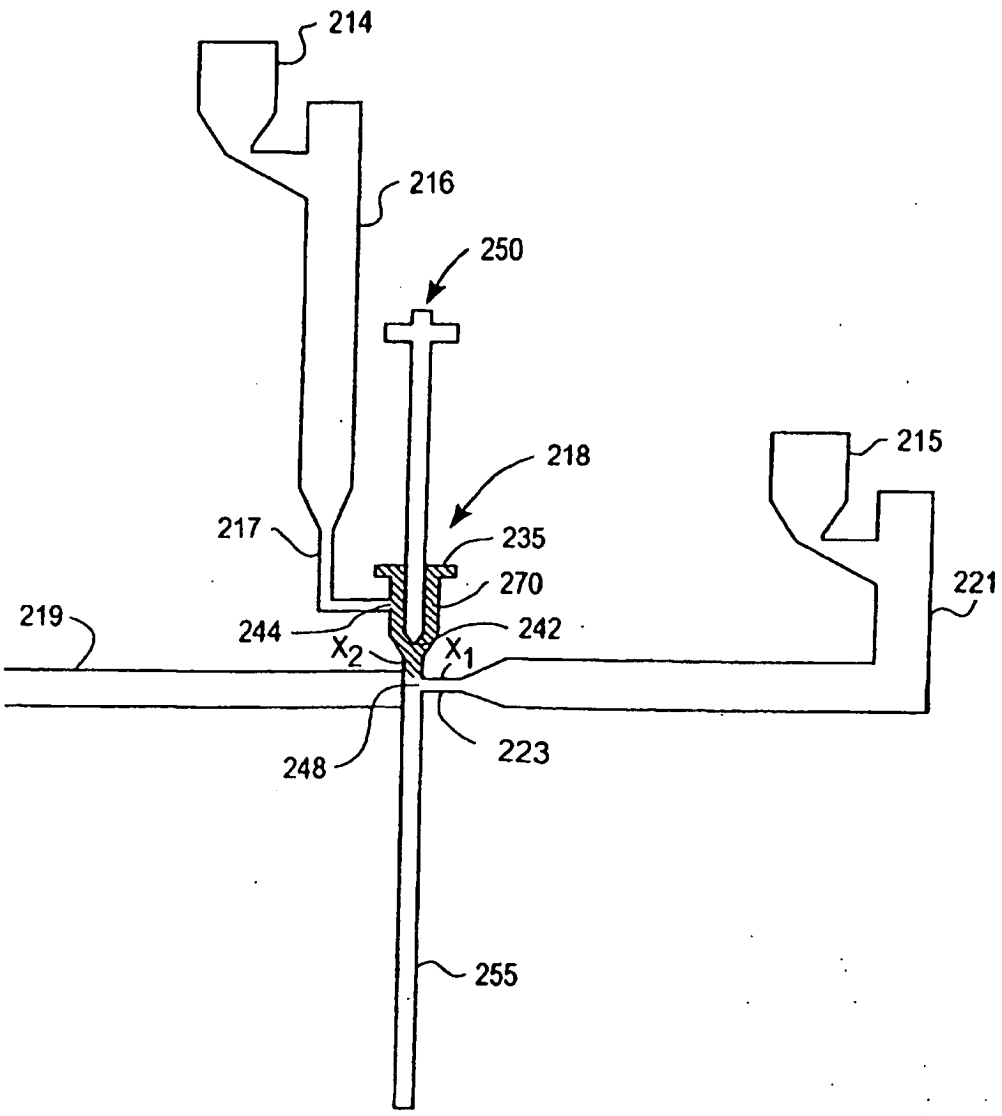

FIG. 32

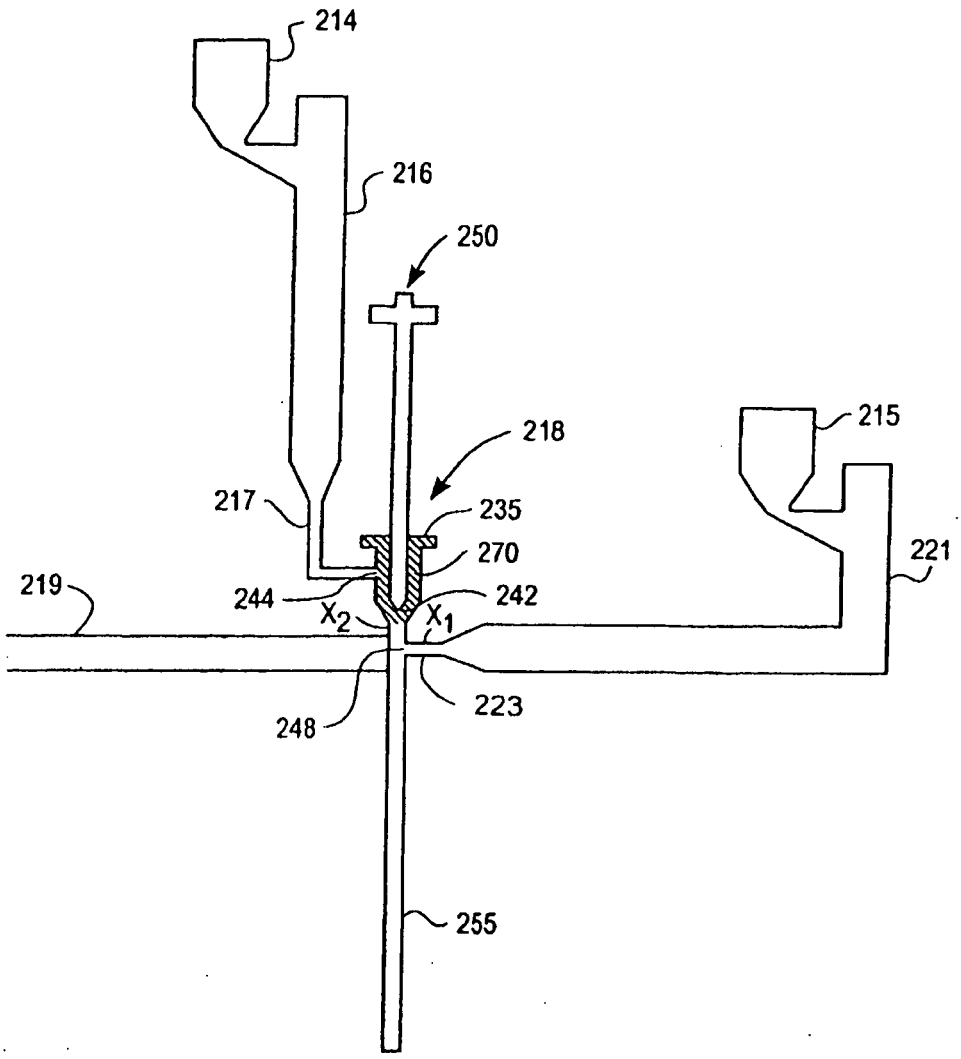

FIG. 33

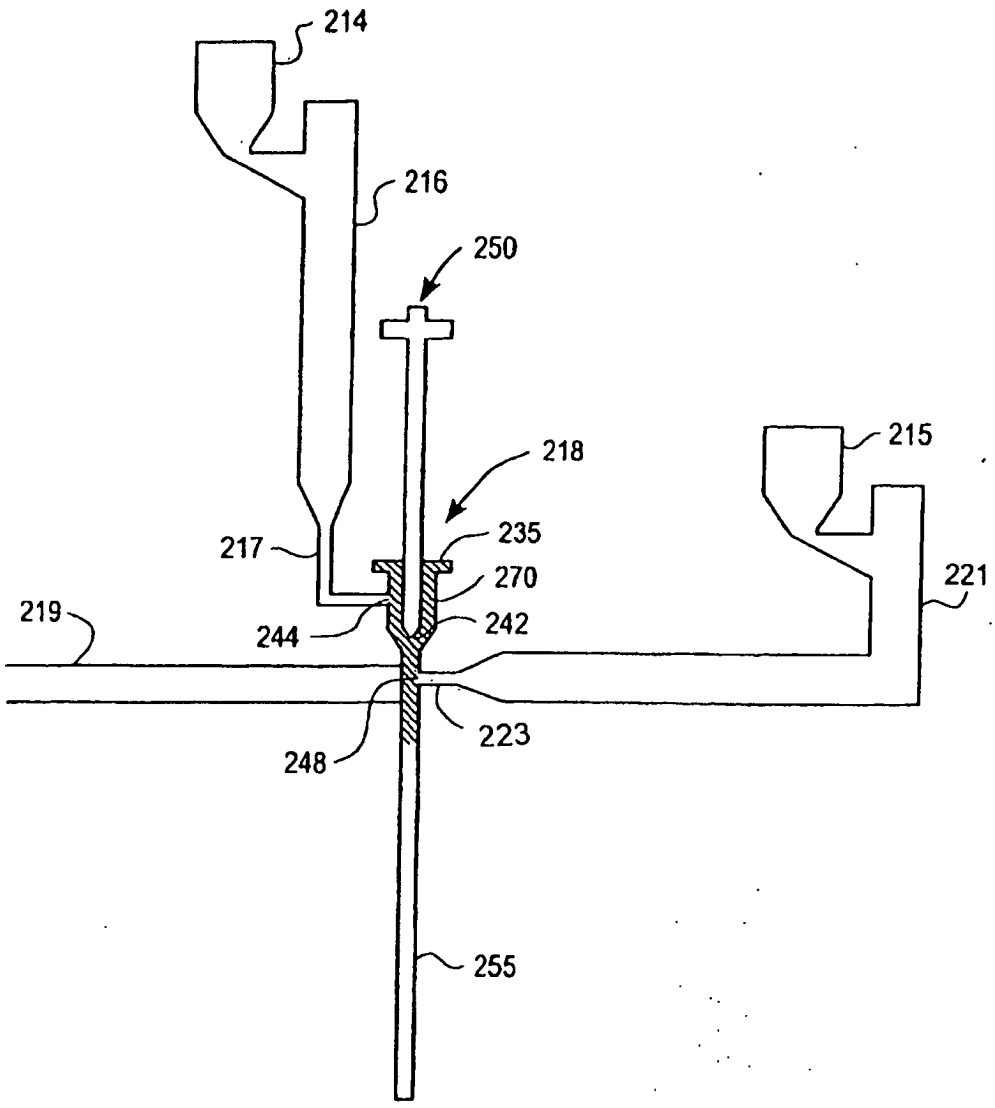

FIG. 34

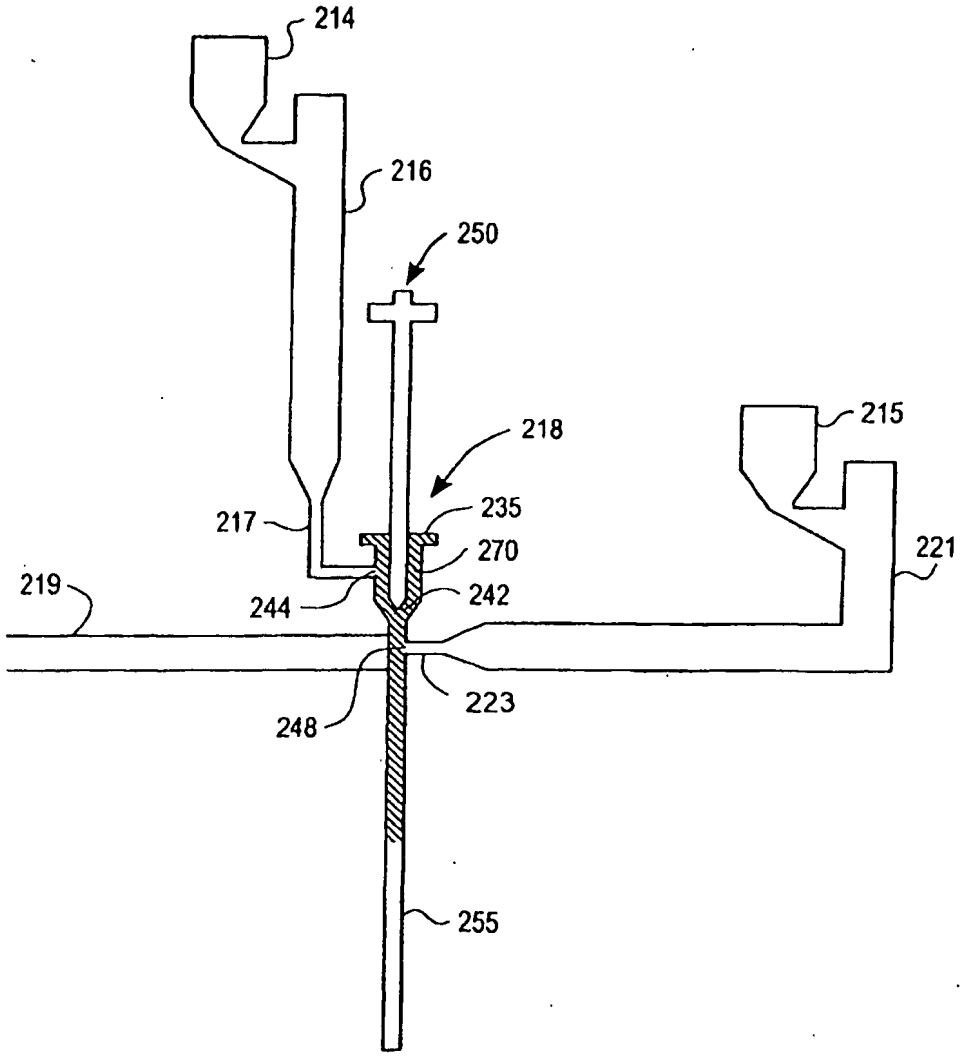

FIG. 35

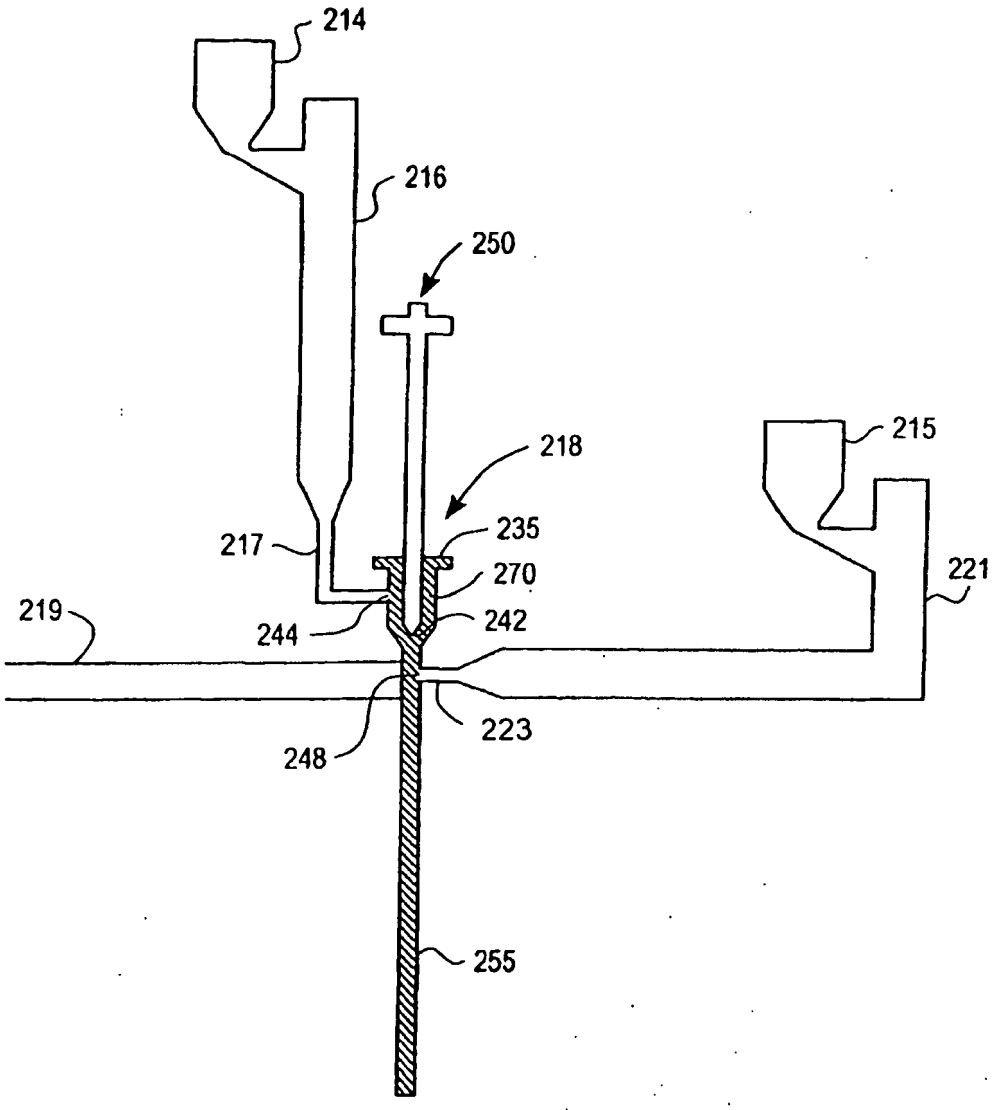

FIG. 36

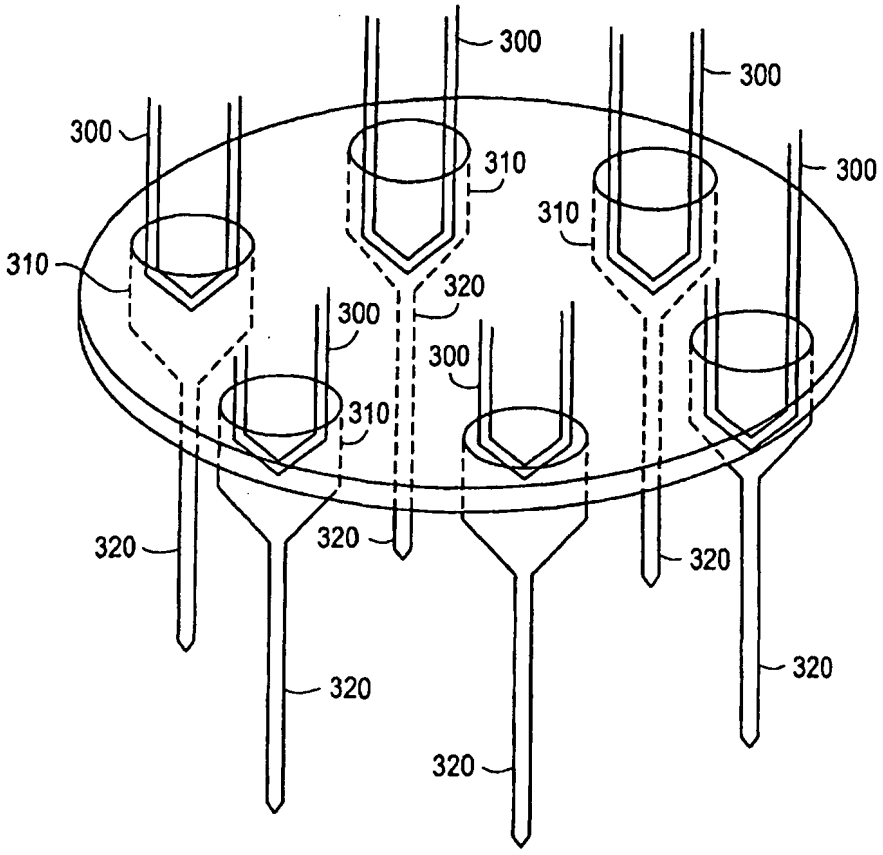

FIG. 37

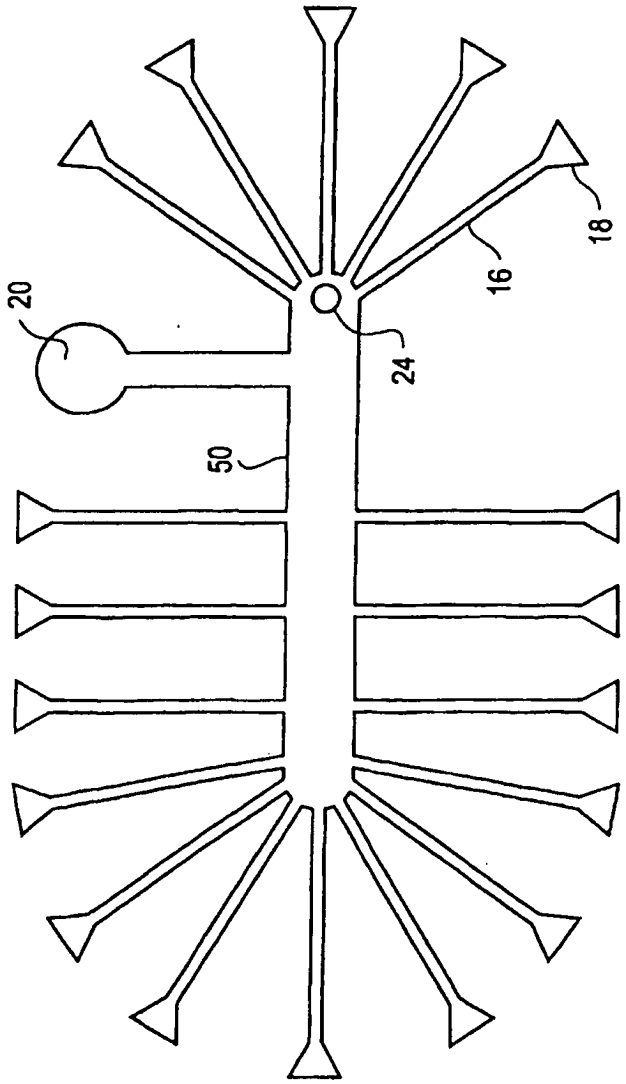

FIG. 38